

**Regulating Medicine:  
A Theoretical Reassessment  
Of The Constitution Of Medical Law**

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In memory of my late grandfather,  
Yannis Gartzios 1916-2000



Nel mezzo del cammin di nostra vita  
mi ritrovai per una selva oscura,  
ché la diritta via era smarrita

**Dante Alighieri, *Divine Commedia***

# TABLE OF CONTENTS

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<i>Acknowledgements</i>	V
<i>Declaration</i>	VI
<i>Abstract</i>	VII

<b>INTRODUCTION</b>	1
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## **CHAPTER 1:**

<b>“The Doctrinal Delineation Of Medical Law”</b>	9
<b>A. Introduction.</b>	10
<b>B. On doctrinal definitions.</b>	12
1) The methodological preconditions of the doctrine.	12
2) The aim and methodology of my critique.	16
<b>C. A critical portrayal of the main doctrinal delineations.</b>	18
1) Medical law and ethics.	18
a) The core of the argument.	18
b) The critique.	21
i. The conceptual objection.	21
ii. The jurisprudential objection.	23
2) Medical law and human rights.	25
a) Preliminary remarks.	25
b) The socio-political background of the argument.	27
i. Medicine as science.	28
ii. The rise of individualism and the emergence of the human rights discourse.	34
c) Refining the human rights argument.	36
d) The critique.	39
i. The constitutional objection.	39
ii. The empirical objection.	44
iii. The conceptual objection.	47
<b>D. Conclusion.</b>	50

## CHAPTER 2:

<b>“The Empirical Complexity Of Medical Law”</b>	52
<b>A. Introduction.</b>	53
<b>B. The selection of the relevant material.</b>	55
<b>C. The normative content of medical law.</b>	60
1) Case law.	60
a) Consent to treatment.	60
b) The best interests principle.	65
c) Medical negligence.	70
d) Information disclosure and its relationship to negligence.	77
e) Medical confidentiality.	81
2) Legislation.	83
a) Subject-specific legislation	83
i. Mental health.	83
ii. Reproduction.	85
iii. Organ donation and transplantation.	88
iv. Medical research.	90
v. Miscellaneous.	91
b) The regulation of health care provision.	93
i. The regulation of health care professionals.	94
ii. The structure of the NHS.	95
iii. The regulation of public health.	98
<b>D. The modus operandi of the courts: models of judicial reasoning.</b>	99
1) <i>Re C (adult: refusal of medical treatment)</i> .	100
2) <i>Sideway v. Bethlem RHG (HL)</i> .	102
3) <i>Gillick v. West Norfolk &amp; Wisbech AHA (HL)</i> .	107
4) <i>McFarlane and Another v. Tayside Health Board</i> .	110
5) <i>R v. Cambridge District Health Authority, ex p B (CA)</i> .	113
<b>E. Conclusion.</b>	116

**CHAPTER 3:**

<b>“Legal Regulation From a Systems-Theoretical Perspective”</b>	119
<b>A. Introduction.</b>	120
<b>B. Complexity as an object of theoretical enquiry.</b>	121
<b>C. Law as a social system.</b>	126
1) Basic concepts.	126
a) System and environment.	127
b) The level of programming.	131
c) Redundancy and variation.	134
d) Interrelation of systems through interference and structural coupling.	139
2) The function of law.	142
3) Interim conclusions.	147
<b>D. On regulation.</b>	148
1) Regulation in the political system.	148
2) The notion of the regulatory trilemma.	150
3) Redundancy and variation revisited.	155
4) The stabilisation of expectations in the temporal dimension.	155
5) The notion of reflexive law.	158
<b>E. Conclusion.</b>	161

**CHAPTER 4:**

<b>“Medical Law In Search Of Its Object”</b>	164
<b>A. Introduction.</b>	165
<b>B. Medicine from a systems-theoretical point of view.</b>	166
1) The institutional dimension of medicine: the economic system.	168
2) The technical dimension of medicine: medicine as a subsystem of science.	170
<b>C. Structural coupling through medical risk.</b>	174
<b>D. The internal constitution of medical law.</b>	176
1) Preliminary remarks.	176
2) The doctrine revisited.	177
3) Redundancy and variation in action.	179
a) Medical negligence.	181
b) Consent to treatment.	183
c) The best interests principle.	185

4) On the stabilisation of expectations (again).	186
5) An endnote: reflexivity in medical law?	188
E. Conclusion.	189
 <b>BIBLIOGRAPHY</b>	 191

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## DECLARATION

I declare that:

- (a) this thesis was composed by myself;
- (b) the work presented here is my own, except where stated; and
- (c) the work has not been submitted for any other degree or professional qualification

Alexios Tattis

**ABSTRACT**

The gradual regulatory orientation of law towards the sphere of medicine is generally believed to have led to the occurrence of a new legal discipline, namely medical law. Although the sociological study of law has revealed the complex repercussions of regulation, the emergence of medical law during such a process has attracted very little attention. This inevitably calls into question its precise identification.

My argument begins from within the discipline of medical law. First, I consider the doctrinal propositions regarding the subject matter of medical law and then the content of the legal norms that belong to it. As far as the question of the constitution of medical law is concerned both perspectives are problematic: the former because the conceptualisations it proposes are themselves contested or contestable and the latter because the relevant legal norms reveal a field of intense complexity that requires further analysis.

These problems make it necessary to theoretically re-assess questions of definition and delineation. Based on insights from systems theory, especially from the work of Niklas Luhmann and Gunther Teubner, I argue that the most fruitful way to conceptualise medical law should be based on an understanding of law as an autopoietic social system. This understanding challenges the way that medical law is traditionally perceived, defines the link between law and medicine in terms of structural coupling and highlights the problems that the regulatory exposition of law to medicine generates for the new discipline.

Within this framework, this thesis claims that medical law is constituted internally, in the process of the legal involvement with medicine; also, that its constitution is ingrained with disintegrative effects that threaten the normative potential of this new branch of the law.



# Introduction

Hardly a week passes without the announcement of something new from the field of medicine. The public domain is in effect bombarded with the possibility of new therapies and new drugs and with revelations regarding the future potential of medical research. This is not to say that the public can easily draw a line between the real value of “good news” and the possible exaggerations in its representation in the media.<sup>1</sup> Yet, it cannot be seriously disputed that advances in biology and information technology have indeed enhanced very significantly the potential of medicine. This is especially the case in particular areas, like infertility treatment, organ transplantation and what can be depicted commonly as “gene therapy”.<sup>2</sup> More generally though, the whole apparatus of medicine has been much benefited by a number of important scientific discoveries.

Yet, all is not bright in the realm of medicine. Its promise for human betterment, highly intensified by the advances just described, is accompanied by a certain societal uneasiness especially regarding the repercussions that a whole-hearted endorsement of what medicine can achieve may entail. This is not necessarily a surprise: arguably, it is just a particular instance of the scepticism that has accompanied science and its claims of progress, referring in particular to the unanticipated consequences of specific developments.<sup>3</sup> It may even be an indication of the human tendency to treat with suspicion and mistrust anything that appears as radically new.<sup>4</sup> Whatever the reason for this uneasiness, what is important is that it has generated a societal call for monitoring medical progress. Modern medicine is not to be left alone; rather it should be monitored by society. In practical terms, this call for control has taken the shape of a general consensus that medicine must be *regulated*. It is exactly at this point that the law has been brought into the picture as the most obvious means through which societal and political influence over medicine can be achieved.

Now, the involvement of the law with medicine is not a new phenomenon. During the course of the 20<sup>th</sup> century, the law was mobilised in a number of areas, most

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<sup>1</sup> This point hints towards the interesting question of how the public perception of science is influenced by its representation in the media. For discussion, see S. Allan, *Media, Risk and Science* (Buckingham: Open University Press, 2002), A. Petersen, “Replicating Our Bodies, Losing Ourselves: News Media Portrayals of Human Cloning in the Wake of Dolly” (2002) 8(4) *Body and Society* 71 and A. Irwin and B. Wynne (eds.), *Misunderstanding Science? The Public Reconstruction of Science and Technology* (Cambridge: Cambridge University Press, 1996).

<sup>2</sup> This is a somewhat vague term that refers to a variety of different things. For a useful overview, see M. Cavazzana-Calvo *et al.*, “The Future of Gene Therapy” (2004) 427 *Nature* 779 and J. Kinderlerer and D. Longley, “Human Genetics: The New Panacea?” (1998) 61 *MLR* 603, pp. 614ff.

<sup>3</sup> For an introduction to this tendency, which is especially acute during the second part of the 20<sup>th</sup> century and is ultimately linked with the sociological concept of *risk*, see M. David, *Science in Society* (New York: Palgrave, MacMillan, 2005), pp. 38-50.

<sup>4</sup> This can be further justified if one takes into account that at least some of the new developments appear able to revolutionise the understanding of the very nature of the human species. The possibility of human cloning is an obvious example here.

notably in the protection of public health, in the establishment of a comprehensive national health service and in the provision of remedies against medical malpractice. Moreover, if one explores further into the past, it is obvious that a close connection between law and medicine is by no means a novelty of our time. Still, it is striking that historically their “relationship” was mainly complementary, in the sense that medicine was often providing assistance to law – forensics is the obvious example.<sup>5</sup> More recently a *qualitative* shift has occurred: their relationship is more than often confrontational, since the law is involved as a regulatory institution.

A crucial characteristic of this qualitative shift in the current situation is the sheer *quantity* of legal interference. This is the most manifest indication of the major intensification in the control of medicine through law. Legal prescriptions are now relevant for almost everything that happens within the field of medicine and refer not only to the aspects of medicine resulting from the scientific developments of the day, but also to those that used to exist and were traditionally beyond the scope of legal regulation.<sup>6</sup> Against such a background, it is unsurprising that a new, autonomous branch of the law is deemed to have come into existence. This branch is usually depicted under the term *medical law* and is the subject of specialised academic study and legal practice.

I will dwell on the *mode* of the academic study of medical law and it is here that the initial trigger in writing this work can be found. Since the beginning of the development of interest in the study of medical law (which can probably be traced back to the late 1970s), the thrust of the relevant intellectual efforts has mainly been oriented to the investigation of *particular* issues. These are either general “themes” that are overwhelmingly significant for the field (like consent to treatment) or concrete instances of medical practice that have generated a legal response (for example organ transplantation). It is the accumulated outcome of such efforts that has gradually “produced” the discipline of medical law. Yet, and with no intention to disregard the very real significance of these efforts, something is missing from such a picture, namely a coherent account of what exactly is the nature of medical law as an autonomous discipline. Although it is well accepted that medical law exists as a distinct branch of the law, it remains unclear exactly how or on what conditions this branch is *constituted* as

<sup>5</sup> For a detailed discussion of the collaboration between law and medicine in the past, see M. Clark and C. Crawford (eds.), *Legal Medicine in History* (Cambridge: Cambridge University Press, 1994).

<sup>6</sup> It is instructive to contrast the current degree of law’s interference with medicine with the following passage of the dictum in *Farquhar v. Murray* (1901) 3F, 859, 862, in the beginning of the 20<sup>th</sup> century:

“This action is certainly one of particularly unusual character. It is an action of damages by a patient against a medical man. In my somewhat long experience, I cannot remember having seen a similar case before.”  
(cited in the introduction in D. Giesen, *International Medical Malpractice Law* (Dordrecht: Martinus Nijhoff, 1988)).

such. While it is acknowledged that it is a relatively new discipline, its autonomous existence is deemed to be almost self-evident: it is somewhat assumed that medical law acquires its distinct character as a result of the regulatory orientation of law towards medicine and crucially because the law responds in a particular and highly complicated way to a set of *externalities* emanating from the sphere of medicine. This general assumption is apparent even in academic textbooks regarding medical law, where the main focus lies consistently in the exploration of particular themes and much less on the question of the constitution of the discipline.<sup>7</sup>

This *under-theorising* is unfortunate for a number of reasons. First, it undermines the importance of the novelty of the discipline by taking its existence for granted. Secondly, it conceals the fact that the unearthing of the constitution of the discipline as something to be problematised, can very much enrich the extant theorising on particular issues by providing additional dimensions to them. This becomes even more significant, if one considers that the existing apparatus of medical law is a patchwork of norms that did not develop in an orderly manner but rather as a result of essentially random legislative interventions and judicial decisions. Thirdly, and in my view most importantly, it is responsible for the lack of interest in examining whether the mere identification of an external trigger that generates a legal reaction is enough to serve as an organising principle for the constitution of any branch of the law – and this is exactly the case with the identification of medical law so far. I insist that this issue is crucial because if this assumption does not hold true, then our understanding of what medical law is becomes wide open again and a general reassessment of the discipline in its entirety is necessary.

Within this framework, the primary aim of my thesis is to provide an argument about the *constitution of medical law*, with a particular emphasis on questioning the premises on the basis of which this has so far been understood. I will do this by taking into account the extant proposals regarding the subject matter of the discipline, by assessing whether or not these are plausible or not and by providing a different perspective on the question. It goes without saying that this whole enterprise is based on a set of theoretical tenets regarding the very nature of law as a social phenomenon.

The starting point of my analysis is indeed the idea that medical law is a new discipline that results from the gradual intensification of the involvement of law with medicine. Given that at least ostensibly the emergence of medical law is an instance of a

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<sup>7</sup> It is interesting to note here that one of the few attempts to compile a history of how the discipline has come into existence and how “medical” or “health” law has been so far defined can be found in a work that is not interested in providing a comprehensive presentation of the discipline, namely in T.K. Hervey and J.V. McHale, *Health Law and the European Union* (Cambridge: Cambridge University Press, 2004), pp. 11ff.

phenomenon of legal growth, the concept that dictates the orientation of my thesis is that of *juridification*, and the treatment of my initial question derives from theories that have dealt extensively with it. These theories acknowledge the importance of externalities for the law, but handle them in a much more refined way than the assertion that the law merely reacts to external events.

Juridification is a term coined with the aim of depicting the phenomenon of legal expansion, in particular when this refers to the legal regulation of a social domain previously unregulated. So, it is not only the proliferation of norms that is important but also the respective novelty of the fact that these norms refer to a particular social area. The relevant theorising is indeed broad, yet its most interesting insights treat juridification as an indication of the general structural traits of the society within which the phenomenon is identified.<sup>8</sup> This means that juridification is seen as intrinsically linked with the particular political organisation of a given society and the concept can be used as a tool for exploring the transformation of the relationship between the legal and the political domain as they co-exist and co-evolve in time.<sup>9</sup> Along these lines, Jürgen Habermas has argued that in Western societies it is possible to identify four distinct “juridification thrusts” that have occurred in accordance with different types of political ordering, namely what he calls the *bourgeois state*, the *Rechtsstaat*, the *democratic state* and the *welfare state*.<sup>10</sup> He effectively claims that the juridification phenomenon identified in the last part of the 20<sup>th</sup> century can be explained in terms of the particular positioning of the law within the remit of the welfare state. If one takes into account that the welfare state is essentially characterised by *interventionist* tendencies,<sup>11</sup> it is not difficult to conclude that the law, which can be used as an instrument for affecting social change and implementing policies, expands its regulatory gamut in accordance with the scale of the policy choices of the welfare state. Such a formulation explains legal expansion through the *instrumental* use of the law by the welfare state.<sup>12</sup>

<sup>8</sup> See in details G. Teubner, “Juridification: Concepts, Aspects, Limits, Solutions” in G. Teubner (ed.), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labour, Corporate, Antitrust and Social Welfare Law* (Berlin: Walter de Gruyter, 1987), pp. 3-48 with many further references.

<sup>9</sup> For a classic account of legal evolution along these lines see P. Nonet and P. Selznick, *Law and Society in Transition: Towards Responsive Law* (London: Transaction Publishers, 2001, originally published by Harber Torch Books in 1978).

<sup>10</sup> See in details, J. Habermas, *The Theory of Communicative Action (Volume 2, Lifeworld and System: A Critique of Functionalist Reason)* (Cambridge: Polity Press, 1989), pp. 357ff.

<sup>11</sup> For a short but informed analysis of the particular characteristics of the welfare state, see J. Tweedy and A. Hunt, “The Future of the Welfare state and the Social Rights: Reflections on Habermas” (1994) 21 *Journal of Law and Society* 292.

<sup>12</sup> For an introduction to the widely discussed issue of legal instrumentalism, see R. Cotterrell, *The Sociology of Law: An Introduction* (2<sup>nd</sup> edition, London: Butterworths, 1992), pp. 44ff.



In linking legal expansion with the welfare state through the concepts of juridification and legal instrumentalism, an initial platform for exploring the original aim of my thesis emerges. This platform dictates that the constitution of medical law as an autonomous discipline can be established only if one considers seriously the problems that relate to legal instrumentalism. The implication here is that to understand the constitution of medical law, it is necessary to investigate what are the *repercussions* for the law by its instrumental use by the welfare state. If this point of view is further pursued, a number of interesting questions come to the surface. Among them, three particular issues are of primary significance:<sup>13</sup> a) the impact of this instrumentality on legal rationality and most importantly, on the exact balance between formal and substantive elements in the law of the welfare state;<sup>14</sup> b) the identification of the limits of what the law can achieve when used in an instrumental way, since it is not necessarily the case that the law can indeed bring forward any policy that the political domain defines as worth pursuing and c) the identification of ways through which the regulatory potential of the law can be enhanced, especially in the light of the possibility that this potential may be at the outset limited in accordance with (b). Naturally, these are all open questions and the answer that one is willing to provide depends very much on one's theoretical allegiances. In what follows, I will tackle these issues using a version of *systems theory* that has been proposed by Niklas Luhmann and further expanded by Gunther Teubner. This is not an arbitrary choice. It is justified because systems theory insists on the importance of the link between the law and its external environment, a link that is at the core of the constitution of medical law, as this is hitherto perceived. Yet, it treats this link in a very sophisticated way that reveals a number of exciting possibilities that have not so far received any special attention. In anticipation of what will be discussed in detail in the course of the thesis, let me just say that systems theory proposes a much more complicated process of interaction between the different spheres of society. This does not obey the logic of direct influence (that is consistent with the current understanding of medical law), but is controlled by mechanisms that are *internal* to the spheres that interact.

By incorporating these additional questions and this theoretical tradition into the original aim of my thesis, I am now in a position to refine its scope. What I intend to do

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<sup>13</sup> For reasons that justify the choice of these particular issues see G. Teubner, "The Transformation of Law in the Welfare State" in G. Teubner (ed.), *Dilemmas of Law in the Welfare State* (Berling: Walter de Gruyter, 1986), pp. 3-10, *passim*.

<sup>14</sup> For this issue, see the classic discussion in G. Teubner's, "Substantive and Reflexive Elements in Modern Law" (1983) 17(2) *Law and Society Review* 239.

is to reassess the constitution of medical law as it emerges as a discipline from the interaction between law and medicine: although this should not be understood as a direct interaction, it dictates exactly how the law responds to medicine and how it organises itself when doing so. This reassessment is further determined by the parallel understanding of what are the consequences for the law of the intensification of its exposure to medicine, and of what its possible limitations are, when it seeks to provide regulatory solutions to medicine. In a sense, the provision of an answer to these latter questions constitutes the secondary aim of my thesis. However, this statement must not lead to the false impression that we are dealing here with distinct issues: the constitution of medical law ultimately depends both on the impact that medicine has on the law and on the regulatory potential of the law towards medicine.

This thesis is organised along the following lines. The substantial discussion follows a tripartite structure: the first two chapters consist in the “unpacking” of the discipline of medical law as it now stands and in accordance with the doctrinal propositions regarding its subject matter. Then, the third chapter provides the theoretical tools in terms of which the discipline should be reassessed. Finally, this reassessment appears in the fourth chapter where the theoretical conclusions reached in chapter 3 are applied to the discipline of medical law as this has been described in the first two chapters.

To be more precise, in the first chapter of the thesis, I will discuss the doctrinal aspect of medical law and I will focus especially on the doctrinal attempts to define the *scope* and the *subject matter* of medical law. I will explore the preconditions of these doctrinal propositions and through them I will identify two as the most dominant, namely one that defines medical law in terms of medical ethics and one that does so in terms of human rights. I will discuss in some detail the relevant propositions and I will provide a critique of their insights. On the basis of this critique, I will argue that the doctrinal delineations of the field of medical law are not satisfying for a number of reasons and that the question of how the field is indeed constituted remains open.

In the second chapter, I will focus my attention explicitly on the legal norms that have so far crystallised the legal regulation of medicine. In presenting them in detail, I do not simply intend to show the empirical reality of the norms, the proliferation of which is linked with the emergence of medical law. Rather, I will make use of this presentation to reach a number of preliminary conclusions regarding the regulatory orientation of the law towards medicine that these norms reveal.

In the third chapter, I will present the theoretical framework in terms of which I will reassess the field of medical law. It is here that I will heavily rely on systems theory and on the concept of juridification and that I will clarify my own position regarding several contested issues within this theoretical tradition. In particular, I will insist on the idea that the interaction between law and medicine, on which the emergence of the discipline of medical law depends, should be understood as a relationship between autonomous and, crucially, *self-referential*, *autopoietic* systems. This core idea provides the opportunity to be aware of the fact that the relationship between systems should not be taken for granted and accordingly to investigate in detail both the exact conditions of the constitution of autonomous branches within the law and law's limitations whenever it is mobilised as a regulatory agent. In this latter task, the concept of the *regulatory trilemma* will be particularly useful.

In the final chapter, I will proceed in the reassessment of the field of medical law, making use of the insights provided by systems theory, as these will have been explored in chapter 3. In doing so, I will also revisit the conclusions reached in the discussion in chapters 1 and 2. Through the combination of these insights, I will make clear my own proposals regarding the constitution of medical law and the regulatory potential of the law when dealing with medical issues. These proposals will be summed up as *six* particular theses.



# **Chapter 1**

## **The Doctrinal Delineation Of Medical Law**

## A. Introduction.

The aim of this chapter is in effect quite clear. What I intend to do here is to take into consideration the doctrinal aspect of medical law and to investigate what, if anything, this source can contribute to the main question of my project, namely the constitution of medical law. In the general introduction to the thesis, I have identified the resort to the doctrine as the first step in unpacking the discipline. This is indeed a self-evident choice. My claim that it is necessary to reassess how medical law is constituted cannot be sustained without considering how this question has already been tackled within the discipline. Even though I have implied that the academic study of medical law has under-theorised the issue (an implication that will hopefully be justified in the course of this chapter), it is at the doctrinal level that one must start.

Before engaging in any substantive discussion, it is necessary to take a moment and reflect on the notion of doctrine. This is vital, because although the term “doctrine” is ever-present in any kind of legal analysis, its exact meaning remains ambiguous. Arguably, the term signifies the theoretical work that legal scholars, judges and lawyers are undertaking when analysing or investigating legal norms, but this very loose definition leaves a range of questions unanswered, basically the main “function” of the doctrine and the methodology on the basis of which doctrinal work takes place.

For the purposes of my discussion, I maintain that the role played by the doctrine is one of “gathering” already existing legal data, with the aim of assessing them theoretically and of projecting the relevant conclusions into the future.<sup>1</sup> This process is not arbitrary, but it takes the form of a *rational reconstruction* of legal data.<sup>2</sup> This means that whoever is engaged in doctrinal analysis, does so in conformity with a simple or complex rational ideal (whatever this may be) on the basis of which her particular analysis of legal data becomes meaningful. The exact criteria in terms of which such work is conducted are irrelevant here. What is relevant is that they are often determined in accordance with the particularities of the field of law within which doctrinal work takes place and that they reflect a set of principles or values that are deemed compatible or highly significant for this field. This assertion is simply the logical consequence of the idea of rational reconstruction: the rational ideal that sustains such a doctrinal reconstruction is not arbitrary but is already embedded in the branch of the law that the legal data under

<sup>1</sup> See in more details A. Peczenik, *On Law and Reason* (Dordrecht: Kluwer, 1989), pp. 143ff.

<sup>2</sup> For a thorough discussion of what the methodology of rational reconstruction entails, see N. MacCormick, *Rhetoric and the Rule of Law: A Theory of Legal Reasoning* (Oxford: Oxford University Press, 2005), pp. 29ff.

analysis belong to (or at least is believed to be embedded by the theorist that is engaged in doctrinal analysis).<sup>3</sup>

The idea that the doctrine entails a rational reconstruction, which proceeds on the basis of a set of principles or values, is rather redundant when the theorist is dealing with a “stable” branch of the law. This is because in areas of the law that are persistently seen as autonomous and self-contained (for example tort law), at least some value orientations are solidly embedded. So, these are constantly and implicitly present in any doctrinal work that is relevant for this branch of the law.<sup>4</sup> This is not necessarily the case in novel areas of the law (such as medical law), the distinct character of which is still under development. Here, the value orientations of the relevant growing doctrine are much more important, since it is these orientations that will ultimately determine how the new legal branch will eventually be “constructed”.<sup>5</sup> This should not come as a surprise. Doctrinal work always focuses on the interpretation of legal norms and in doing so it often filters out and defines the crucial factors on the basis of which concepts embedded into norms become *legal institutions*.<sup>6</sup> From then on, and in order to sustain the interpretation of norms further, the doctrine explicitly or implicitly systematises legal institutions into sub-systems or branches of the law.<sup>7</sup> This is exactly what has happened with medical law. Through the interpretation of legal norms that have been the outcome of the regulatory orientation of law towards medicine, legal institutions (like the autonomy of the patient or medical confidentiality) have emerged; then, these institutions have been combined in a manner that sustains the new discipline of medical law.<sup>8</sup>

It follows that to understand how the relevant doctrine has constructed medical law as a new branch of the law, one has to identify the basic value orientations that have been utilised in this process. Since it must be clear by now that these orientations are

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<sup>3</sup> This point is very much compatible with the idea that each branch of the law has a value orientation or that particular branches of the law are “locally” coherent exactly because of a set of principles or values that sustain them. For the former view see N. MacCormick, 2005, p. 114; for the latter see B. Levenbook, “The Role of Coherence in Legal Reasoning” (1984) 3 *Law and Philosophy* 355.

<sup>4</sup> This does not mean that these orientations are uncontested; still, because of their existence, even attempts to challenge them are framed in response to them.

<sup>5</sup> For further discussion of the idea that doctrinal legal study constructs legal “subsystems” on the basis of rational reconstruction of legal material see N. MacCormick, 2005, p. 229 and J. Bengoetxea, “Legal System as a Regulative Ideal” (1994) 53 *ARSP Beiheft* 66.

<sup>6</sup> Here, I use the term “legal institution” in the technical sense employed in N. MacCormick’s, “Law as Institutional Fact” (1974) 90 *The Law Quarterly Review* 102.

<sup>7</sup> This point is consistent with the idea that in modern legal systems norms tend to link together in a purposive manner, an idea that is more clearly expressed in Lon Fuller’s view about law as a purposeful enterprise. For further discussion, see L.L. Fuller, *The Morality of Law* (2<sup>nd</sup> edition, London: Yale University Press, 1969), especially chapter 3.

<sup>8</sup> In this respect, the doctrine works in a *reflexive manner*: it abstracts principles from legal norms, it uses these principles to interpret the norms and ultimately feeds back these principles into the normative horizon of the law as organising structures.

usually implicit, the problem is to find a way to unearth them. In this chapter, I will do that by focusing on the doctrinal attempts *to define a subject matter for medical law*. This is because the definition of a subject matter for medical law captures in a very straightforward way what is deemed to be important for the discipline; in effect, it represents a very concise embodiment of the basic orientations that run across the whole of the discipline. Accordingly, by focusing on the definitional aspects of the relevant doctrine, it becomes much clearer how medical law has so far been constituted as an autonomous branch of the law.

In order to discuss in a constructive way this definitional aspect of the doctrine of medical law, it is indispensable to be clear on the methodological preconditions of any definitional enterprise. This is going to be my focus on the next part of this chapter. In addition, I will clarify the perspective on the basis of which I will assess these definitional attempts. As soon as this is established, I will move on to the substantive analysis and I will discuss in details the two most dominant doctrinal accounts regarding the subject-matter of medical law. I will introduce their main tenets and I will provide a critical account of their merits and disadvantages. Finally in the concluding part, I will summarise my findings and I will provide a final evaluation of the doctrinal constitution of medical law.

## **B. On doctrinal definitions.**

### **1) The methodological preconditions of doctrinal delineation.**

In order to define doctrinally what the subject matter of medical law is, a twofold assumption -common to any definitional endeavour- must be made. In our case, this is that medical law *exists* as a distinct, identifiable phenomenon within the law, and that this “existential identification” is *justified* in the sense that it is neither false nor arbitrary. These two aspects are inherently interwoven into a fundamental problem of *conceptualisation*, which imparts the necessary backbone of any definitional inquiry in such a significant degree that the need to sort it out holds in any case. Although this is a vital problem, the solution to it seems self-evident and, therefore, beyond scrutiny, whenever the phenomenon under investigation is easily identifiable in terms of time and experience. Whenever one feels that it is absolutely clear what one is talking about, the need to consider the conceptualisation problem is very often neglected. To provide a

layman's example: we know what the police force is, or at least we feel that we know what it is. We do not doubt that the police force exists, nor do we feel compelled to justify our perception of its existence. Its presence as a societal institution has endured in time and although we can problematise its societal functioning we are hardly ever sensitive to the conceptualisation problem.<sup>9</sup>

This is not the case, however, for medical law as a phenomenon under investigation. In the general introduction to the thesis I explained that medical law is still a new and probably unstable discipline, which has emerged as a potentially autonomous legal branch in the late 70s or so. Even if it is a distinct discipline, it remains in a process of fluid and quite unpredictable development, still being constituted by an amalgam of diffused legal categories, which are often oriented to arguably different stakes. This is why Derek Morgan has argued that "...the framing of responses properly lying within medical law is ... an intellectual responsibility that lies at the heart of academic obligation".<sup>10</sup> What is important here is that this "instability" of the discipline in question, can often amount to a kind of ontological contestability, which brings forth the problem of conceptualisation in a very acute way.

So, how can we deal with the problem of conceptualisation? This is a question that has been present ever since it was understood that the object of any enquiry is always constituted and that pure description is not possible as such.<sup>11</sup> Rather, the need to identify a phenomenon through a particular conceptualisation is necessarily an *evaluative* process. Conceptualisation can take place only when an evaluative perspective is at work, on the basis of which it becomes possible to identify what are the salient features of the phenomenon under scrutiny. Description does not stand without evaluation: they constitute a mutually dependent pair, in such a manner that the sophistication of the latter determines the depth of the former and vice versa.<sup>12</sup> Yet, it is evaluation that is of primary importance and that is why it is vital to clarify how it happens.

Any attempt to evaluate presumes a process of selection, and any selection is organised according to a *focal point*. This is usually exemplified as the *central case* of the enquiry that has necessitated the evaluation. By locating a central case, main and peripheral issues can be distinguished and further selections and conceptual distinctions

<sup>9</sup> This is not to say that this problem is irrelevant for my example, but only that we usually neglect it. The significance of the problem can be easily seen if one considers the complex academic efforts in the field of the sociology of policing.

<sup>10</sup> See D. Morgan, *Issues in Medical Law and Ethics* (London: Cavendish Publishing Limited, 2001), p. 3.

<sup>11</sup> For a very concise analysis of this hugely discussed fundamental thesis, see amongst many others, J. Finnis, *Natural Law and Natural Rights* (Oxford: Clarendon Press, 1980), p. 3.

<sup>12</sup> For traces of the same argument within the context of medical law, see I. Kennedy and A. Grubb, *Medical Law* (3<sup>rd</sup> edition, London: Butterworths, 2000), p. 3.

can be drawn. Therefore, in order to define what something is, it is indispensable to identify its focal point. This identification is also based on an evaluative process and, thus, it also depends on the application of evaluative criteria. Now, the selection of these criteria depends on the *viewpoint* from which the relevant investigation departs. Since all investigations are oriented to the achievement of a particular aim, this viewpoint is usually a *practical* one, interwoven with the *raison d'être* of the investigation.<sup>13</sup> Having established a particular practical viewpoint, and through that a central case and thus a focal point, more relevant features can be settled and ultimately a "phenomenon" can be delineated as something distinct. To put it in a summarised way, in order to identify something, it is necessary to consider its focal point, in terms of which specific selections unfold. This focal point emerges according to the practical viewpoint that informs the relevant definitional enquiry.<sup>14</sup>

This "formula" illuminates the necessary preconditions of any effort to identify an object of investigation, but reveals only the formal features of providing definitions. Now, how exactly these features unfold in actual scenarios, depends on the nature of what is to be defined and on the context from within which definitions occur. Since it is the doctrinal definition of a subject matter for medical law that is of interest here, what must be further examined is how these features have informed the relevant doctrinal analysis.

Before doing this, a word of caution is necessary. Although the doctrine of medical law has been generally sensitive to the conceptualisation problem presented herein, the reader should not assume that clear solutions can be traced easily. We should recall that the doctrine focuses on the assessment of legal norms and does not theorise in a vacuum, but only in close connection with them. Accordingly, the proposed definitions of the subject matter of medical law, and especially the premises that sustain them, must be "distilled" from a general body of academic work that only rarely provides explicit statements regarding the essence of medical law. So, what follows should be understood as the conclusion of my investigation on how definitions about the subject matter of medical law emerge from the relevant doctrine and not as unequivocal doctrinal claims.

Let me start with the practical viewpoint that the doctrine of medical law endorses. This is shaped by the idea that there exists a strong link between law and medicine, which is viewed in basically *evolutionary* and *functional* terms. The premise here is

<sup>13</sup> For an analysis of the concept of "practical view point", see J. Finnis, 1980, p. 12.

<sup>14</sup> For a much more detailed presentation of this argument, which goes back to the Aristotelian tradition, see J. Finnis, 1980, chapter I, with further references.



that medical law emerges as part of an evolutionary process, during which the law expands its scope responding to external, societal influences. Unsurprisingly, the initial stimuli that have generated the birth of medical law are to be found within the sphere of medicine. Since medicine is the pool of events that has generated a legal response, the orientation of law towards medicine is cast in terms of an interaction that (from the point of view of the law) is either reactive or proactive, but that in any case positions the law at the receiving end of medical signals. In turn, this interaction is further refined according to a functional perspective. The signals emanating from medicine typify instances of conflict, which “require” resolution. It is exactly this need that ultimately justifies the instrumental involvement of the law, which is to function as a mechanism for the resolution of problematic situations within medicine.<sup>15</sup>

In close connection with this duality of evolution and function, doctrinal propositions regarding possible focal points for medical law can then be identified. These focal points appear exactly as propositions regarding the *subject matter of medical law* and they substantiate the underlying practical viewpoint, by referring to the actual interaction between law and medicine. A crucial point here is that the existence of this interaction cannot in itself be taken as a focal point: this would be too crude, not least because the realm of medicine is itself a dynamic and ever-changing plateau. A simplified deference to the link between law and medicine would not provide evaluative identification, but only unqualified description by begging the question of what is really meant by the link. This means that ultimately (albeit again implicitly), the doctrine of medical law is based on a set of assumptions regarding the state of affairs within modern medicine and takes a view on the issues that have acquired central significance for medicine. Therefore, a conceptual account of medicine itself is present in a shadowy form in many instances of doctrinal work and this account is itself liable to selections in accordance with which medicine is described. In this respect, the doctrine of medical law depends very much on particular agendas regarding medicine, determined by the theoretical and political allegiances of the individuals that engage in doctrinal theorising. What is crucial, thus, is that the doctrinal conceptualisations of medical law tend to mirror particular conceptualisations of medicine: it is the latter that determine the main medical “themes” that invite legal response and trigger a doctrinal process of analysis that ultimately constitutes medical law as a distinct branch of the law.

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<sup>15</sup> Therefore, it can be argued that the doctrinal practical viewpoint coincides with an explicitly liberal account of law, according to which the law is essentially an instrumental regulatory device *outside* the realm of medicine. For this point, see, in details, J. Montgomery, “Time for a Paradigm Shift: Medical Law in Transition” (2000) 53 *Current Legal Problems* 363, at pp. 363-364.

On the basis of these premises, two main propositions have emerged from the doctrine of medical law that identify a subject matter/focal point for the discipline. They are both shaped by the same practical viewpoint; however, being informed by different conceptualisations of medicine, they reach different conclusions as to what this subject matter is and they define medical law in a different way. The first proposition is based on a perception of modern medicine as a social sphere that constantly generates ethical dilemmas. Therefore, the subject matter of medical law is the law's involvement with medical ethics and the discipline is organised as something distinct according to this subject matter. The second proposition conceives of medicine as a field of intense power imbalances that open up the possibility of abuse of patients; this necessitates their protection and, accordingly, the subject matter of medical law is the protection of patients through the mobilisation of a shielding mechanism. This has been found in human rights apparatus. As a coda, let me stress the following point that is probably already clear: both these doctrinal propositions<sup>16</sup> do not merely delineate an area of interface between law and medicine. More crucially, through the definition of a subject matter for medical law, they provide the initial basis for the development of a derivative set of concrete orientations that are necessary for sustaining and ultimately constituting medical law as an autonomous branch of the law.

## **2) The aim and methodology of my critique.**

It is time to conclude this part of the chapter by identifying more clearly what I intend to do from now on. In the substantive discussion that follows in the next part, I will examine at length the two conceptualisations of medical law already identified and I will expose their respective merits and shortcomings, focusing specifically on a set of objections that diminish their plausibility. This examination is the necessary first step for my own reassessment of how medical law is constituted: it represents the evaluation on whether the doctrinal constitution of medical law as an autonomous discipline holds. If indeed it holds, then no further effort is necessary. If it does not, as I contend, then the issue opens up again.

As far as the methodology of the subsequent discussion is concerned a number of caveats must be clearly stated in advance. The first is that I will accept the premises of the doctrinal definitions as they stand. In particular, I will not challenge at all the practical

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<sup>16</sup> For reasons of brevity, in the course of this chapter I will refer to the first proposition as "the medical law and ethics approach" and to the second as "the human rights approach".



viewpoint that underlies the relevant doctrine, namely the dual premise of legal evolution and function. This means that in what follows I will treat as correct the view that medical law is constituted as a result of law's response to external events emanating from medicine and that these events are also the matrix of organising principles *for* medical law. So, I am accepting here that in the constitution of medical law there is a strong correspondence between what is happening in medicine and the main orientations of medical law, exactly as the relevant doctrines concede. This being the case, my objections will take the form of an essentially internal critique that will challenge the doctrinal propositions on their own methodological terms. More precisely, these objections will focus on whether the underlying conceptual understanding of medicine is itself accurate as a definitional basis for medical law, and on whether the proposed link between law and medicine on the basis of medicine's conceptualisation is plausible in real terms (since once again the doctrine is constantly determined by the actual legal material). This is just a very general categorisation of my objections, which, in addition will concentrate on a number of ostensibly different issues. Indeed, what follows can be challenged as uneven. However, my objections are designed to be compatible with the particularities of each of the propositions and I concede that they do not constitute a coherent schema as such.

The second caveat is that in the development of my objections, I will respond not only to explicit arguments that sustain the relevant propositions, but also to the logical consequences that these propositions entail if explored further. This may invite against my arguments the criticism that I challenge views that are not necessarily shared by those that support the relevant definitions. However, in developing, for instance, the idea that the subject matter of medical law is the regulation of medical ethics, it is important to consider the repercussions of this argument as far as possible, even if advocates of the proposition are not aware of its consequences. In my view this investigation is crucial for the final evaluation of the merit of their argument, notwithstanding whether they do or do not accept its consequences. This strategy is further justified because of the primarily implicit nature of doctrinal delineations: exactly because the propositions that I am discussing here are distilled from analyses of particular norms and judicial decisions, my attempt to assess them must go beyond the original intentions of their "promoters".

With these remarks, the exposition of my methodology is concluded. It is now time to turn to the substantive discussion.

## C. A critical portrayal of the main doctrinal delineations.

### 1) Medical law and ethics.

#### a) The core of the argument.

The high stakes of medical practice and the intimate character of the doctor-patient relationship have traditionally attached a high degree of moral concern to medicine. This concern has been explicitly manifested in the drafting of guidelines of professional ethics<sup>17</sup> for doctors and in the constant reoccurrence of public debates regarding the ethical significance of a variety of medical procedures.<sup>18</sup> Within this framework, the emergence of a distinct sub-category of general ethics, the so-called “medical ethics” or - more recently- “bioethics”<sup>19</sup> comes as no surprise.

In the course of history, significant moral dilemmas have emerged because of particular scientific and socio-political occurrences. Such occurrences tend to stimulate the moral debate, often resulting in calls for immediate moral resolution and an increase of public feeling that medicine is a morally sensitive enterprise. For instance, during the 19<sup>th</sup> century, the advent of palliative care and the discovery of ether transformed to such a degree the delivery of care that a whole range of new moral issues came to the surface. More recently, the unprecedented medical atrocities that the world witnessed during the Second World War<sup>20</sup> also triggered a very intense moral debate. The more apparent post-war response was the radical transformation of the whole area of medical research and experimentation, which became the subject of detailed scrutiny and regulation.<sup>21</sup>

<sup>17</sup> Let me briefly clarify here the difference between “morality” and “ethics” so that confusion is avoided: morality is a first-order concept that refers to the need to distinguish between what is right and wrong in practical situations. “Ethics” is a second-order notion that refers to the justification process according to which morally relevant choices are made. For further analysis, see J.K. Mason and G.T. Laurie, *Mason & McCall Smith's Law and Medical Ethics* (7<sup>th</sup> edition, Oxford: Oxford University Press, 2005), p. 4.

<sup>18</sup> For example, see documents as the *Declaration of Helsinki*, adopted by the World Medical Assembly, Helsinki, Finland 1964 (as amended in Edinburgh, 2000), and the *International Code of Medical Ethics*, as amended in Venice, 1983.

<sup>19</sup> For an analysis of the differences between the two terms, and for a presentation of the historical course of the ethics of medicine, see A. Jonsen, *The Birth of Bioethics*, (Oxford: Oxford University Press, 1998).

<sup>20</sup> For a detailed presentation of the issue, see R. Proctor, *Racial Hygiene: Medicine Under the Nazis* (Cambridge: Harvard University Press, 1987) and J.R. Lifton, *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (New York: Basic Books, 1986). However, it is interesting to note here that the medical atrocities of Nazi Germany were not a unique policy of a particular totalitarian regime; rather they were the tragic apex of widespread social policy developments in the whole western Europe during the 1920s and 1930s. For a historical analysis, see M. Mazower, *Dark Continent: Europe's Twentieth Century* (London: Penguin Books, 1998), chapter 3; also, J. Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World*, (London: Victor Gollanz, 1998), pp. 107ff., especially regarding the popularity of the “eugenics” movement in USA in the same period.

<sup>21</sup> The first document that tackled the issue was the *Nuremberg Code* of 1947.

Arguably, the rapid development of medical technology throughout the latter half of the 20<sup>th</sup> century and beyond, and the variety of new potentials and possibilities that have enriched the medical arsenal has generated new and ongoing moral concerns. The intensification of medical interventions during the process of procreation, the gradual decoding of the human genome with its potentially radical therapeutic capability, the realisation of organ transplantation and even the possibility of postponing the end of life when the organism itself is unable to survive independently are all new developments that raise various moral problems, some of them unthinkable only 30 years ago. Indeed, it appears that medicine has acquired the potential to re-address issues of elementary moral and philosophical importance,<sup>22</sup> issues that challenge our fundamental beliefs regarding the nature of the human species and even touch upon the metaphysical realm. It seems that we have entered a new era, or, as Jeremy Rifkin has declared, a “biotech century”.<sup>23</sup>

The difficulties in tackling and in providing plausible positions on moral dilemmas are intensified given the moral pluralism of modern western societies. In such an atmosphere, it is not surprising that the law has been brought into the picture as a societal mechanism that can contribute to the alleviation of this problem. To understand what this legal involvement implies, let me provide the following distinction: the law can either be seen as a normative edifice, the content of which mirrors the main moral assertions of a given society and thus re-enforces them whenever they face a challenge or as vehicle for the provision of morally relevant answers in the sense that either directly or indirectly it provides justifications or reasons for action that are ethically sound. The difference here is that in the first case the law is ethically informed whereas in the second it is a forum that shapes the ethical domain in accordance with its content and procedural structures.<sup>24</sup> In both cases, though, the law is intimately connected with ethics. In implicit harmony with this view, authors like Kenyon Mason and Michael Davies,<sup>25</sup> treat medical law as a valuable forum for exploring normatively the moral difficulties of modern medicine. Accordingly, the regulatory horizon of medical law is invested with a

<sup>22</sup> See the very thorough analysis in T. Beauchamp and J. Childress, *Principles of Biomedical Ethics*, (5<sup>th</sup> edition, Oxford: Oxford University Press, 2001); also, L.M. Silver, *Remaking Eden: Cloning and Beyond in a Brave New World* (London: Weidenfeld & Nicolson, 1998).

<sup>23</sup> See in details his 1998, *passim*.

<sup>24</sup> This distinction does not exhaust the possibilities of the link between law and ethics: a further option comes from the point of view of ethics and can be expressed as the ethical evaluation of legal norms.

<sup>25</sup> See J.K. Mason and G.T. Laurie, 2005, especially chapter 1 and M. Davies, *Medical Law*, (2<sup>nd</sup> edition, Blackstone Press Limited, 1998). Other authors also advocate this idea albeit more implicitly: for instance, see J. McHale and M. Fox, *Health Care Law: Text and Materials* (London: Sweet and Maxwell, 1997).

significant moral responsibility,<sup>26</sup> since the orientation of law towards medicine is essentially linked with medical ethics. This does not mean that the exact degree of legal intervention is at the outset defined; however, even this remains an open question,<sup>27</sup> it very much depends on the particularities of the moral situation of the day. The logical consequence of this view is that medical law is to a very significant extent constituted as the sum of the legal responses to the moral questions emanating from the sphere of medicine and that as a distinct legal discipline it represents an efficient way of balancing conflicting individual interests within a community of moral pluralism.<sup>28</sup> It goes without saying that this “moral responsibility” of the law is expressed differently in accordance with the concrete issue that is under regulation. Sometimes, the law becomes involved directly with scenarios that are obviously complex from a moral point of view and when it does so, the legal solutions that are provided very much resemble ethical justifications; the decision in *Re A*,<sup>29</sup> where a court had to decide the tragic fate of two Siamese twins is an obvious example here. In other scenarios, the moral sensitivity of the law is much subtler. Yet, even cases of medical negligence can be read in the light of ethics, if one is ready to accept that the formulation of the relevant legal rules represents an ethically sound solution to the question of how responsibility for negligence should be allocated.

Generally speaking, this proposition regarding the subject matter of medical law is strengthened, considering that a significant number of legal principles (that significantly shape the relevant legal norms) are very close to similar ethical principles. For instance, values like autonomy, beneficence (exemplified in the best-interests principle), sanctity of life, dignity, privacy, solidarity and justice<sup>30</sup> are all present in the norms belonging to medical law. Indeed then, the argument that the organising orientation of medical law is its close connection with the domain of medical ethics sounds ostensibly plausible.

<sup>26</sup> As a further indication of this tendency, let me stress that even judicial pronouncements often embrace one or the other version of a strong link between law and ethics. For instance Hoffmann LJ, in *Airedale NHS Trust v. Bland* [1993] 1 All ER 821, at 858 explicitly stated that “... I would expect medical ethics to be formed by the law rather than the reverse”.

<sup>27</sup> For this point, see in details J.K. Mason and G.T. Laurie, 2005, pp. 1-3 and 23ff.

<sup>28</sup> However, it has been argued that there is no actual guarantee that the law can regulate within a context of moral pluralism, on the basis that when there is no consensus about what is morally plausible, it is rather improbable that the law will provide a “satisfying” solution. For this argument see T.K. Hervey and J.V. McHale, *Health Law and the European Union* (Cambridge: Cambridge University Press, 2004), p. 13.

<sup>29</sup> *Re A (children) (conjoined twins: surgical separation)* [2000] 4 All ER 961, 57 BMLR 1.

<sup>30</sup> For this “list” see further J.K. Mason and G.T. Laurie, 2005, p. 4; also the detailed analysis in T. Hope *et al.*, *Medical Ethics and Law: The Core Curriculum* (Edinburgh: Churchill Livingstone, 2003), chapter 3.

## b) The critique.

The conceptualisation of medical law with reference to medical ethics is undoubtedly a very serious attempt to highlight the significance of ethics for modern medical practice. The main force of this proposition is exactly that the ethical aspect of medicine *is* important and becomes even more important as new technological achievements come forward. This being the case, this proposition is crucial in opening up the relevant debate and in proposing legal solutions to particular problems.

Nevertheless, this section investigates this argument solely in terms of the plausibility of the conceptual orientation of medical law to medical ethics; in other words, of the plausibility of the core proposition that medical law must be conceptualised as a discipline in a strong connection with the domain of medical ethics. It seems to me that at this level of analysis, the project of linking medical law with medical ethics is problematic. In this section, I will analyse the reasons why I believe this is so, by presenting two distinct objections; the first is conceptual in nature, whereas the second is jurisprudential.

### *i. The conceptual objection.*

The doctrinal proposition that I am discussing is based on a particular perception of medicine, namely that medical practice is a social domain that generates moral conflicts and dilemmas. This particular “conception” of medicine is of course selective, since it focuses only on some aspects of its practice. I do not intend to challenge this selectivity, since this is always necessary for any attempt to make sense of a complex social domain and for locating a core theme within it. However, the very idea of selectivity leaves open the question of its adequacy. This depends very much on whether the proposed conceptualisation represents the actuality of the domain under investigation in a *significant* degree, especially according to the way that this actuality is relevant for the aim of the original enquiry generating the whole process. In our case, the original enquiry is the constitution of medical law: it is in reference to this, that I will argue that this perception of medicine is problematic.

Essentially, even the implicit idea that medicine is a social domain flooded by morally significant issues does not easily accommodate those aspects of the everyday routine of medicine that still invite legal interference although they are morally neutral.



The point here is that medical practice is not always characterised by moral dilemmas, irresolvable disagreements and contested possibilities. Although nobody explicitly disputes this, the proposition that medical law is about medical ethics neglects that the vast majority of the actual instantiations of medicine consists of settled practice and established methodology. Within such a framework, conflicts that demand legal intervention occur, but these are not necessarily moral in nature. By no logical necessity should every conflict be construed as an ethically significant conflict or as a conflict the moral resolution of which is inherently problematic. This being the case, the proposition I am criticising treats the everyday routine of medicine as less significant and focuses on rather marginal scenarios. This is not to say that I believe them to be unimportant, only that by being marginal they cannot provide the basis for a comprehensive representation of the field. To put it bluntly, the attachment of medical law to medical ethics fails to integrate the interference of the legal system with the morally neutral aspects of medicine and “suffers” from a displacement of the central case of medicine.<sup>31</sup>

At a further level of analysis, the insistence on highlighting the ethically significant aspects of medicine tends to underestimate the complexity of different *stakes* that shape medical practice. Martyn Evans has thoroughly argued<sup>32</sup> that an exclusive focus on the ethical aspect of medicine obscures the range of “values” that drive modern medicine and take them out of the public domain. His point is that other values also exist in medicine and that these are not necessarily linked with either morality or ethics. For Evans, these values are shaped in accordance with socio-political, intellectual and even aesthetic concerns. Consequently, the proposed focus on the moral aspect of medicine alone, not only misrepresents the exceptional as regular, but also oversimplifies the complicated value-horizon of medicine, by insisting on a single-dimensional account.

Finally, at a further level of sophistication, it can be argued that the proposition I am challenging is based on a rather “crude” understanding of the exact nature of the morally significant aspects of modern medicine. Essentially, it takes for granted that the moral dilemmas, which supposedly generate a legal reaction, *are* truly there, that they are easily identifiable as problems, and that they are well known but unfortunately irresolvable without the help of the law, essentially because of the apparent lack of moral

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<sup>31</sup> Similarly, the proposition fails to explain those cases where existing moral issues do not generate a legal response. For example, in the case of resource allocation within hospitals, which undoubtedly causes moral concern, the law just accepts the exercise of discretion by the hospital authorities.

<sup>32</sup> See in details, M. Evans, “Philosophy and the Medical Humanities” in E.M. Evans and I.G. Finlay (eds.), *Medical Humanities*, (London: BMJ, 2001), with further references.

consensus within a pluralistic society. However, this is not necessarily the case. Morgan<sup>33</sup> has argued that modern medicine has been transformed in such a degree that traditional moral stakes are no longer self-evident or ever relevant and that our conception of medicine in accordance with traditional moral concepts is significantly mistaken. Crucially, the very identification of the moral questions that are (or should be significant) within medicine is itself a contested moral issue the resolution of which presupposes a new ethical -or, more accurately, *meta-ethical*- justification. In other words, what is nowadays problematic is not only the first-order resolution of moral questions in medicine, but also the second-order identification of what exactly counts as a moral question to be tackled. The second-order problem invites philosophical and epistemological concerns that, once again, the proposition I am criticising neglects. This is a significant omission, because a call for the intervention of the legal system, which is ultimately based on the need to tackle moral questions must necessarily accept that at least the relevant moral questions are firmly established *as* questions. If this is itself contested, it does not follow that the law can fulfil the function that is ascribed to it. The situation becomes much more complicated and the assumed link between medical law and medical ethics becomes much more difficult to sustain.

In my view, all these arguments weaken the merits of the definition of the subject matter of medical law in terms of the link between law and medical ethics. Evidently, this definitional proposition correctly highlights the need to be alert to the morally significant aspects of modern medicine, but by insisting on a conceptual understanding that tinges medicine in a particular, morally oriented way, it misses other aspects of it, equally significant as far as the law is concerned. This *under-inclusiveness* already diminishes the validity of this definition of medical law. There is however another argument that further challenges its plausibility.

## *ii. The jurisprudential objection.*

The main jurisprudential assumption that underlies this proposed definition of medical law is that the legal and the moral sphere do (or at least can) indeed interface. So, the idea that medical law is constructed as a discipline in close connection with the domain of medical ethics, almost takes for granted that, notwithstanding what the exact content of the degree of this connection is, law and morality contribute to their mutual shaping.

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<sup>33</sup> See, D. Morgan, 2001, pp. 18-20.

More importantly, in the case of medical law this “fusion” of law and morality seems to be not only unquestionable but also normatively desirable.

A very strong objection, here, is that this close interface between law and morality is not as self-evident and free of problems as this definitional proposition has to believe in order to stand. In jurisprudential terms, the link between law and morality is a thoroughly discussed and hugely contested theoretical matter<sup>34</sup> that has given rise to a variety of concrete issues, none of which enjoys a unanimously acceptable answer.<sup>35</sup> For my purposes, the most crucial question that has to be dealt with is exactly the plausibility of the assumption that the law *can in fact* take on board and provide regulation for and solutions to moral issues. Leaving aside the general question of the desirability of law’s involvement, what should be considered seriously is the very potential of the law to respond to moral dilemmas and to provide authoritative guidance to the ethical domain. If this possibility is contested (as is the case) the assumed coincidence between law and morality that serves as the basis for conceptualising the discipline cannot be taken for granted.

In order to evaluate the plausibility of the proposed coincidence, one needs to take into account several complex issues like the exact nature of these two normative orders, the essence of their inherent logic, the difference between the finality of law and the open-endedness of morality,<sup>36</sup> the often particularistic character of morality against the universalistic character of the law,<sup>37</sup> their respective claims for validity, their actual social function etc. Against such a complex background, it is fair to argue that an understanding of medical law, which perceives its link with medical ethics as self-evident, ignores the crucial theoretical difficulties that this link has to confront and ultimately fails to appreciate that, perhaps, the link does not hold. Essentially, by not being based on a clear account of *how* medical law truly interacts with medical ethics, this definitional proposition falls short of credible, complete analysis and therefore its plausibility itself is seriously undermined.

If these arguments hold, then, both at a conceptual and at a jurisprudential level, this definitional proposition is inadequate in providing a plausible conceptualisation of the discipline of medical law. Although the focus on medical ethics is important, it

<sup>34</sup> The degree of the relevant theoretical complexity is such that it is very surprising that this particular understanding of medical law only marginally discusses it. See, for example, the very brief account of M. Davies, 1998, pp. 10-12.

<sup>35</sup> The most controversial of which seems to refer to the problem of the validity of the legal system and has initiated the well-known debate between positivistic and natural law theories.

<sup>36</sup> For an analysis of the importance of finality for the law, see N. MacCormick, 2005, chapter 13.

<sup>37</sup> For further discussion of this arguably contestable point see J. Dancy, *Ethics Without Principles* (Oxford: Clarendon Press, 2004).



cannot be that the subject matter of medical law is the legal tackling of problems of medical ethics, for the reasons presented so far. As a result, further investigation is necessary; the subsequent part of the chapter continues the inquiry by focusing on the next major proposition regarding the subject matter of medical law.

## **2) Medical law and human rights.**

### **a) Preliminary remarks.**

Arguably, the most popular doctrinal proposition regarding the core of medical law relates the discipline to the realm of human rights. Once again, the starting point is that medical law should be perceived as a legal response to a morally “sensitive” context,<sup>38</sup> which here takes a very specific form: it emanates from the realisation that the patient is the weakest party of medical interactions and that she is actually sensitive to an array of possible ways of exploitation.<sup>39</sup> This specific concern differentiates this proposition from the one advocating the general orientation of medical law to the domain of medical ethics and confers on it a much more concrete character. Instead of a variety of ethical considerations, the main stake here is the demand to protect the patient,<sup>40</sup> a demand so fundamental that necessitates a thorough exploration of the range of potentially protective measures.

The first step towards securing protection is to ascertain that the power to determine what will take place should rest with the patient. This could recompense for her weaker status, since, being able to decide for herself, the patient acquires control over her own fate. However, this idea represents simply a desirable state of affairs and an actual protective mechanism must be invoked to secure it. At this point, the legal system is summoned as the obvious protector and it is asked to validate this moral stake with its particular prescriptive force. Since decision-making is the main issue, the obvious tendency is to highlight the importance of the values of self-determination and autonomy<sup>41</sup> and to ensure that the law guarantees that patients ultimately decide for

<sup>38</sup> For the argument that this approach can be seen as a particularised version of the general concern regarding the ethics of medical practice, see T.K. Hervey and J.V. MacHale, 2004, pp. 23ff.

<sup>39</sup> The description of the patient as “a vulnerable object of exploitation” is indeed quite old. See, for instance, T. Parsons, *The Social System* (London: Routledge and Kegan Paul Ltd, 1951), p. 445.

<sup>40</sup> I refer here to the core of the proposition alone; this can be expanded towards the need to protect not only patients, but also fetuses or even other parties.

<sup>41</sup> The literature regarding autonomy and its connection with self-determination is immense; very thorough insights can be found in A. McCall-Smith, “Beyond Autonomy” (1997) 14(23) *Journal of Contemporary Health and Policy* 23; T.E. Hill, Jr., *Autonomy and Self-Respect* (Cambridge: Cambridge University Press, 1991); G. Dworkin,

themselves.<sup>42</sup> It is exactly this need that justifies the appeal of an inherently protective tool of the legal system, namely the human rights apparatus, and explains the recasting of the issue as a quest for a *right* to self-determination.<sup>43</sup> This is not a random choice; the whole argument is based on the belief that the system of human rights can provide significant protection because it has emerged, historically, as a shield against the abusive power of the exploitative state and, thus, seems to guarantee a higher level of protection than the ordinary correlations of rights and duties of private law,<sup>44</sup> which of course remain relevant.<sup>45</sup>

From this starting point, almost all the aspects of medical practice can be recast as loci of potential infringements of the human rights of the patient. Authors like Ian Kennedy, Andrew Grubb, Margaret Brazier and others<sup>46</sup> have pursued this line of argument and have identified, admittedly to different degrees of explicitness, *medical law as a sub-category of human rights law*.<sup>47</sup> In other words, medical law is the organised crystallisation of the application of the human rights apparatus on the practice of medicine. In the course of time, the relevant arguments have gone beyond the original focus, namely the right to self-determination, and have integrated human rights in a detailed manner into the sphere of medicine, exploring in its generality the possibility of human rights infringements and the significance of a wide set of specific rights. Within this framework of expansion, Brazier has identified four potential loci of human rights concern, namely the patients' entitlement to treatment, their involvement in the choice of

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*The Theory and Practice of Autonomy* (New York: Cambridge University Press, 1988); C.M. Cluvert and B. Gert, *Philosophy in Medicine* (New York: Oxford University Press, 1982).

<sup>42</sup> This is why J. Montgomery has argued that the proposition I am discussing has emerged as a response to a social atmosphere of "highly rational ethical consumerism". In his view, and given that decision-making is the main issue, the question is translated into who will have the power to rationally make a choice of ethical significance. See, in details his "Medical Law in the Shadow of Hippocrates" (1989) 52 *MLR* 566.

<sup>43</sup> The importance of self-determination as a plateau of significant tension regarding who has the authority and the autonomy to make decisions within the doctor-patient relationship has been thoroughly discussed by J. Katz in *The Silent World of Doctor and Patient* (London: The Johns Hopkins University Press, 2002, first published by First Free Press, 1984), especially in pp. 85-86.

<sup>44</sup> For the argument that the human rights apparatus has become so popular because it is something more than the system of ordinary rights, see M. Brazier, *Medicine, Patients and the Law* (3<sup>rd</sup> edition, London: Penguin Books, 2003), p. 28.

<sup>45</sup> For the protective remedies that can be found within private law, see J. Montgomery, *Health Care Law* (2<sup>nd</sup> edition, Oxford: Oxford University Press, 2003), pp. 74ff.

<sup>46</sup> See, amongst many others, I. Kennedy, *Treat Me Right* (Oxford: Oxford University Press, 1991), chapter 20, again I. Kennedy and A. Grubb, 2000, pp. 3ff, M. Brazier, 2003 and S. McLean, *Old Law, New Medicine: Medical Ethics and Human Rights* (New York: Pandora, 1999). Important contributions can also be found in B. Toebes, "The Right to Health" in A. Eide *et al.* (eds.), *Economic, Cultural and Social Rights* (The Hague: Kluwer, 2001); J. Mann *et al.*, "Health and Human Rights" (1994) 1 *Journal of Health and Human Rights* 7; L. Westerhall and C. Phillips (eds.), *Patients' Rights: Informed Consent, Access and Equality* (Stockholm: Nerenius and Santerus, 1994); M. Brazier, "Rights and Health Care" in R. Blackburn (ed.), *Rights of Citizenship* (London: Mansell, 1993).

<sup>47</sup> I am not implying that these authors neglect in their work other possible aspects of medical law; whatever is said in this section refers strictly to their proposal regarding the proper conceptualisation of the discipline.

treatment, the role of the state and the commercial interests within modern medicine,<sup>48</sup> which according to her summarise the key areas of medical law.

The attention of these authors rests on legal concepts overtly related with the protection of the patient and, quite naturally, with legal provisions directly concerned with human rights, like the Human Rights Act 1998 and a set of European and International Conventions that also provide human rights protection.<sup>49</sup> Additionally, they investigate in general the apparatus of public law, which is also understood as a means for achieving individual freedom and self-determination, against possible abuses. Essentially, what matters for the whole argument is the combination of patients' rights with the need to scrutinise intensely what doctors and other health professionals do, since their actions can constitute a source of potential infringements. Through the gradual realisation of the idea that the power of doctors is not beyond control, it is hoped that the patients will be free of abuses and, more generally, of any kind of misconduct. In this respect, this approach represents an essentially *political* agenda, which addresses a particular imbalance of power.<sup>50</sup> Ultimately, it is hoped that through the involvement of the human rights apparatus, the fulfilment of the patients' reasonable expectations from doctors and health care professionals will be guaranteed.<sup>51</sup>

In order to evaluate critically the validity of this complex argument, it is necessary to take a step back, and to explore its sociological and political background in depth. Having established that, it will be possible to further clarify not only the assumptions that serve as the basis of the argument, but also its exact substance. My critique will follow on that basis.

## **b) The socio-political background of the argument.**

To a very significant extent, the occurrence of this definitional proposition "parallels" a set of different, but interconnected social processes that refer to the social status of professional medicine and to the general social atmosphere within which it is practised. One could identify two main background developments, which inform this proposition:

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<sup>48</sup> See M. Brazier, 2003, p. 17.

<sup>49</sup> For an analysis of the relevant provisions emanating from the institutions of the European Union, see T. K. Hervey and J.V. MacHale, 2004, pp. 24ff; for the international framework of protection, see J. Mann *et al.*, *Health and Human Rights: a Reader* (London: Routledge, 1999), *passim*.

<sup>50</sup> Let me stress once again that this is rarely expressed in explicit terms.

<sup>51</sup> For the kind of expectations that develop within the doctor-patient relationship, especially in terms of the impact that the status of the doctor has on them, see M. Brazier, 2003, p. 6.

the first is the integration of medicine into the realm of science and the second is the rise of individualism.

*i. Medicine as science.*

In the course of history, professional medicine has been the subject of various “metamorphoses”<sup>52</sup> that differentiated its scope, its practice and its social status.<sup>53</sup> For contemporary medicine the most defining of these transformations is its gradual integration into the realm of science. To practise medicine is no longer a technical skill, which only complements in various degrees of efficiency the eventualities of fate.<sup>54</sup> Rather, it has become the actualisation of a particular domain of science, it is based on scientific knowledge and it assumes that the practitioner, the doctor, is an expert scientist. This integration of medicine into science has tied the fate of the latter to the fate of the former to such a significant degree that the societal status of medicine parallels completely the societal status of science, as this is defined by the public and scholarly understandings of what science is about.

To be more exact, the intricate linkage between medicine and science has generated a set of *effects*, which have significantly altered the social standing of professional medicine. For the purposes of my discussion, I am interested in particular in a crucial “double effect”. This effect is the tangible result of medicine becoming ingrained into science and it is directly rooted in the steady differentiation of the status of the domain of science that has occurred during the last quarter of the 20<sup>th</sup> century and beyond. The transformation that I am talking about refers mainly to the perception of science in society: it can crudely be defined as the gradual withering away of the idea that science is a neutral enterprise that can undoubtedly contribute to human flourishing, in favour of the idea that science is value-laden and that it has its dark sides, in the sense that scientific developments also have negative consequences.<sup>55</sup> Therefore, science should not only be applauded but also scrutinised as any other human enterprise. The

<sup>52</sup> I borrow the term from D. Morgan, 2001, pp. 13ff.

<sup>53</sup> For an introduction to the history of medicine, see J. Katz, 2002; T. Amundsen, “Physician, Patient and Malpractice: An Historical Perspective” in H. Engelhardt and S. Spicker (eds.), *The Law-Medicine Relation: A Philosophical Exploration* (Dordrecht: Reidel Publishing, 1978) and E. Freidson, *Profession of Medicine: a Study of the Sociology of Applied Knowledge* (New York: Harper Row, 1970).

<sup>54</sup> This differentiation is usually depicted as the transformation of medicine “from art into science”. See, S. McLean, 1999, pp. 5ff and for further analysis J. Katz, 2002, p. xlvii. Also, regarding a more thorough philosophical foundation of the difference between art and science, see J. Finnis, “Natural Law and Legal Reasoning” in R.P. George (ed.), *Natural Law Theory: Contemporary Essays* (Oxford: Clarendon Press, 2002), pp. 134-157, at pp. 139ff.

<sup>55</sup> For this transformation, see in details M. David, *Science in Society* (New York: Palgrave, MacMillan, 2005), especially chapter 3 with many further references.

mirroring of this transformation into the realm of medicine takes the following form: whereas the “traditionally” positive social perception of “objective” science had very beneficial consequences for the social status of medicine and especially for the power that the profession enjoys, the recent and ongoing intensification of science’s scrutiny has also put the practice of medicine under scrutiny.

Both aspects of this effect are very significant for the definitional proposition that I am discussing here and especially the accumulation of power by the medical profession.<sup>56</sup> Accordingly, I will first investigate the issue of power in depth and then I will come back to the issue of scrutiny.

In order to investigate how scientific medicine is linked with power one needs to clarify the possible loci of power within the practice of medicine. Arguably, two such loci can be identified. The first is situated in the actual interaction between a doctor and a patient. The second refers to the general *social* status of the two parties. In both cases the key concept is control; in both cases the doctor is able to exercise control over the patient and, thus, she is in a position of power. Additionally, in both cases this control is linked with *knowledge*, in the sense that it is the scientific nature of the doctor’s knowledge that generates her power to control the patient, as it is the lack of such knowledge that ultimately weakens the patient. To be more specific, in the first case the doctor has *direct* power over the patient, by being able to interfere, often in a very intrusive manner, with the “physical” aspect of human nature, namely with the physiological and anatomical status of the body.<sup>57</sup> In the second case, the situation is subtler and the power *indirect*, although no less significant: the doctor, by defining the condition of the patient and by opining on how she is supposed to behave in order to recover, generates a particular status for her, essentially transforming her into a *patient*. It is after the intervention of a doctor that an individual, who until this point of time simply suffers from certain symptoms, becomes a patient and has to face the social consequences that this new role invites.<sup>58</sup> These consequences vary according to the exact condition of the patient and to

<sup>56</sup> Although in the course of the discussion it would be more accurate to distinguish between the power that the medical profession enjoys as a profession and the power that individual doctors enjoy as individuals, I prefer, for simplification reasons, not to deal with this distinction.

<sup>57</sup> Obviously, this is not the case with recent developments on the provision of medical services, where medical diagnosis and advising can occur through the Internet.

<sup>58</sup> The idea that to be ill and identified as being a patient is not simply a biological state, but essentially a social state has been thoroughly analysed by T. Parsons, 1951, pp. 428ff. and in his “The Sick Role and the Role of the Physician Reconsidered” (1970) 53 (3) *Health and Society* 257. Also, see A. Radley, *Making Sense of Illness: the Social Psychology of Health and Disease* (London: Sage, 1994), E.L. Idler, “Definitions of health and illness and medical sociology” (1979) 13A *Social Science and Medicine* 723 and L. Eisenberg, “Disease and Illness: distinctions between professional and popular ideas of sickness” (1977) 1 *Culture, Medicine and Psychiatry* 9.



lay perceptions,<sup>59</sup> but in any case it is the doctor who has defined this new status and has been in charge of this socially significant transformation.

So, what is the impact of the emergence of scientific medicine on these power structures? Regarding the first plateau of power, two issues are crucial. The first is that scientific medicine takes on board the pace of the development of science in general; it is informed and shaped by rapid scientific innovations, which become part of medical practice by augmenting both the scope and the potential of the technical apparatus of medicine. Scientific developments have given doctors the opportunity to act in a much more complicated, multi-dimensional and sophisticated manner, and have enabled them to deal with the human body in a much more substantial way. Additionally, they have undoubtedly increased the possibility of achieving the desirable aims, by enhancing the chances of success through multiplying the quality of techniques and the possible alternatives.<sup>60</sup> The second point is that the doctor has gradually become an *expert* practitioner, namely a privileged professional who deals with a particular subcategory of scientific knowledge. This kind of knowledge is perceived as a terrain of *expertise* that only professionals, being carriers of expert knowledge and skill, can turn into action.<sup>61</sup> Accordingly, doctors acquire at least a moderate *monopoly* in delivering health-related services and in practising medicine, which now becomes an area of socially significant practice designated almost exclusively for them.<sup>62</sup> Naturally, this achievement is conditioned upon a set of social strategies on the basis of which professional monopoly is indeed established. One can refer to several examples like the use of technical expertise on the basis of which the profession itself defines the standards that judge the competence of its members,<sup>63</sup> even when institutional arrangements that attempt to

<sup>59</sup> See C. Herzlich and J. Pierret, *Illness and Self in Society* (Baltimore: Johns Hopkins University Press, 1987).

<sup>60</sup> I am not implying here that it is self-evident that modern medicine can be proud for achieving a high level of success alone. On the contrary, it has been plausibly argued that medicine is not the only source of the benefits that it claims as its own. For arguments that stress factors like sanitation, lifestyle changes and environmental concerns as importantly contributing to the amelioration of the health of populations, see T. McKeown, *The Role of Medicine* (Oxford: Basil Blackwell, 1979), I. Kennedy, *The Unmasking of Medicine* (London: Allen and Unwin, 1981), pp. 19ff and J. Gray, *Beyond the New Right* (London: Routledge, 1993), pp. 162ff. Even within these lines though, my point is that the emergence of scientific medicine increased the chances of success.

<sup>61</sup> This does not mean that a claim of expert knowledge totally immunises the profession from public control. Especially when medical "scandals" become public knowledge, a crisis in public trust occurs that has deleterious effects for the status of the profession. For such an implication see in detail, J.K. Mason and G.T. Laurie, 2005, p. 14.

<sup>62</sup> This monopolisation of medical expertise is a key factor in understanding the social perception related to the exact status of the professions linked with medical practice. For analysis of the question of professional monopoly see the classic discussion in M. Weber, *Economy and Society*, (London: University of California Press, 1978), pp. 341-343. For further analysis from the perspective of the sociology of the professions see D. Blane, "Health Professions" in G. Scambler (ed.), *Sociology as Applied to Medicine* (4<sup>th</sup> edition, Edinburgh: W.B. Saunders Company, 1997), pp. 212-214; M.S. Larson, *The Rise of Professionalism: a Sociological Analysis* (Berkeley: University of California Press, 1977), pp. 31-39 and R. Murphy, *Social Closure* (Oxford: Clarendon Press, 1988).

<sup>63</sup> For this strategy, see in details, E. Friedson, 1970.

enhance external scrutiny are in place;<sup>64</sup> the establishment of a system of specialised education and training;<sup>65</sup> the particular significance of certification and credentials for the practice of medicine etc.<sup>66</sup> In any case, what is crucial is that as to the first plateau of medical power, scientific medicine has increased what doctors can do and has vested them with the advantage of being the professional group that enjoys a privileged position regarding the relevant practice.

Without ignoring the analysis of the intensification of the direct power of doctors, it is the impact of science on the second plateau of medical power that has attracted much more attention and scepticism, namely the indirect power of the doctor to define the "sick status" of the patient. Far from being simply a biological condition, health and illness are socially significant statuses, which have a direct effect on the individual's social experiences.<sup>67</sup> This being the case, the transition from a state of health to a state of illness is an important social transformation that raises questions of how and under what conditions it happens. Sociological approaches to medicine focus exactly on this transition and, stressing again the more-than-biological nature of health and illness, conclude that it is the outcome of a process of constant evaluation and decision-making, according to which symptoms, diseases and treatments are classified and perpetually re-examined under particular conceptions of what counts or should count as pathological.<sup>68</sup> The main issue here is that the individual in control of this process of evaluation is the doctor who by exercising this evaluation assumes the power to define the social status of the patient.

The integration of medicine into science has increased further this already significant power. To begin with, one has to consider the socially legitimate, self-validating nature of the realm of science. Especially during the domination of traditional notions of "objective" science, there existed a general assumption in favour of its

<sup>64</sup> For the most recent developments regarding these arrangements in the UK, see J.K. Mason and G.T. Laurie, 2005, pp. 15ff.

<sup>65</sup> See R. Murphy, 1988 and M.S. Larson, 1977, p. 68.

<sup>66</sup> For this point, see K.M. MacDonald, *The Sociology of the Professions* (London: Sage, 1995), pp. 161-162.

<sup>67</sup> It is interesting to notice here that the World Health Organisation defines health as a "state of complete physical, mental and social well-being and not merely the absence of infirmity". See World Health Organisation, *The Constitution* (Geneva: WHO, 1948).

<sup>68</sup> For the "evaluative" nature of the concepts of health, disease and illness, see I. Kennedy, 1981, pp. 2-7. This point is simply an aspect of the debate regarding the conceptual ambiguity of these notions; for an introduction to the debate, see C. Boorse, "On the distinction between health and disease" (1975) *Philosophy Affairs* 5; K.W.M. Fulton, *Moral theory and medical practice* (Cambridge: Cambridge University Press, 1989), pp. 25ff; G.W. Bradley, *Disease, Diagnosis & Decisions* (Chichester: John Wiley & Sons, 1993), pp. 1-22; C. Nordenfelt, "On the relevance and importance of the notion of disease" (1993) 14 *Theoretical Medicine* 15; also the contributions in note 58. For arguments against the practical usefulness of this understanding of health and illness see S. Fluss, "The Development of National Health Legislation in Europe: The Contribution of International Organisations" (1995) 2 *European Journal of Health Law* 193 and L. Gostin and Z. Lazzarini, *Human Rights and Public Health in the AIDS Pandemic* (Oxford: Oxford University Press, 1997).



(nowadays hugely contested) value-free nature, whereas its status was based on a kind of “pure”, scientific knowledge.<sup>69</sup> Science was supposed to deal solely with the “objective reality” by investigating concrete physical phenomena, and existed beyond the impact of contextual experiences.<sup>70</sup> Thus, its high significance was essentially sustained on the basis that it does not entail processes of subjective evaluations, but only instances of expert competence. Within this framework, the gradual assimilation of medicine into science has attached to medicine all these postulations and has vested medicine with a kind of a mainstream scientific ideology;<sup>71</sup> traditionally, scientific medicine is also seen as a value-free enterprise, which deals only with the biological and physical aspects of health<sup>72</sup> and which is ultimately based on the scientific competence of the expert doctor. This ideology although already under challenge, still persists and obscures the social aspects of health and illness. As a result the potential for scrutinising the evaluative decisions of what counts as pathological remains in a significant degree hindered.<sup>73</sup> Thus, the power of doctors to define the social status of patients is still very real, but because of the founding assumptions of scientific medicine it is often a neglected power that possibly may escape scrutiny: doctors are even now much more free from the constraints of accountability, at least in comparison with other professions, especially in terms of non-scientific criteria of competence.<sup>74</sup>

This assertion becomes even more significant if one considers the rapid expansion of what counts as medically significant into areas that were traditionally understood as being outside the medical domain. The most obvious example is that of procreation: although infertility was always understood as an eventuality attributed to fate, nowadays it is perceived as a treatable pathological condition, which calls for medical involvement. Other examples include the focus on life choices, the aesthetics of

<sup>69</sup> For a presentation of arguments against this traditional view, see S. McLean, 1999, chapter 1, with additional references and also R. Murphy, 1988, pp. 246-247 where he discusses the problem of scientific knowledge more generally.

<sup>70</sup> For these points, see U. Franklin, “New Threats to Human Rights Through Science and Technology: The Need for Standards” in K.E. Mahoney and P. Mahoney (eds.), *Human Rights in the 21<sup>st</sup> Century* (Dordrecht: Kluwer Academic Publishers, 1993); also, I. Kennedy, 1981, p. 22.

<sup>71</sup> This is why it has been argued that the growth of the professions is contingent upon the advent of an “objective” type of knowledge, which appears to be independent from its socio-cultural context. For this point, see E. Gellner, *Plough, Sword and Book* (London: Collins Harvill, 1988), pp. 51-52.

<sup>72</sup> This is usually referred to as the “mechanical” or “engineering” model of health and illness, which is based on the idea that the human body is healthy when it functions properly, whereas illness is a state of malfunction, emerging due to a specific breakdown (disease) that has to be treated. For an analysis of the main elements of this model, see S. Nettleton, *The Sociology of Health and Illness* (Polity Press, 1995), pp. 3ff.

<sup>73</sup> It has been argued that this is because the idea of scrutiny is attached to particular contexts, whereas science was linked with pure, non-contextual general knowledge. See in details S. McLean, 1999, p. 15.

<sup>74</sup> See S. McLean, 1999, p. 7. Additionally, this lack of accountability could further be explained in terms of lingering elements from the pre-scientific status of medicine, like faith, silence etc. For this point, see J. Katz, 2002, p. 45.

the human body, giving rise to the advent of cosmetic surgery, and even the exploration of genetic identity for various purposes.<sup>75</sup> This process, usually referred to as “medicalisation”, is the outcome of a general social transformation, and can be explained in terms of a variety of reasons, like the professional need to define expansively a medical market<sup>76</sup> and the modernistic tendency to use the flexible concepts of health and illness as governmental strategies, by which populations and individuals are monitored and managed.<sup>77</sup> The emergence of scientific medicine was also an important development in this respect, since it allowed medicine to gain from the pace of scientific developments and to become enriched with new techniques. This facilitated the process of medicalisation, by increasing the range of options that constitute the modern apparatus of medicine and with it the possibility of its expansion.

To summarise the point so far, the integration of medicine into science has increased the power that doctors already enjoyed, in a variety of ways that refer both to the direct and the indirect aspects of this power. Yet an interesting question emerges here: given the arguments regarding the self-legitimizing ideology of science in accordance with its traditional status, how is it possible to recognise the power of the doctors and also to make sense of it as problematic? The answer to this question brings us back to the second aspect of the double effect that I identified at the beginning of this section. Exactly because science steadily loses its very privileged societal status, its ideological structures also lose their impact. Especially as the idea that science as such must now be scrutinised gains in popularity and becomes part of a novel understanding of what science is about, the fate of professional medicine also changes. The power that doctors enjoy is still there; however, the possibility of challenging this power is now socially registered and therefore voices in favour of the need to scrutinise the practice of medicine can proliferate. In this respect, the double effect of the integration of medicine into science is intimately linked with the definitional proposition that I am discussing, since it is connected both with the power of doctors and with the need for control over this power.

<sup>75</sup> In a sense, these examples demonstrate that gradually even the speculative risk of facing an illness, or just an undesirable event have become medically relevant. For this point, see I. Kennedy, 1981.

<sup>76</sup> Which of course happens in parallel with developments in the relevant industries, like the market created by pharmaceutical companies.

<sup>77</sup> This point is linked with the concept of “governmentality”, primary developed by M. Foucault in “Governmentality” in G. Burchell *et al* (eds.), *The Foucault Effect: Studies in Governmentality* (Hemel Hempstead: Harvester Wheatsheaf, 1991); see also his *The Birth of the Clinic: an Archaeology of the Medical Profession* (London: Tavistock, 1976); I.K. Zola “Medicine as an Institution of Social Control” (1972) 20 *Sociological Review* 487; B.S. Turner, *Medical Power and Social Knowledge*, 1987.

Nevertheless, the advent of scientific medicine is not the only social development that has inspired this definition of medical law. Of equal importance was the gradual occurrence of a social tendency in favour of individualism to which I will now turn my attention.

*ii. The rise of individualism and the emergence of the human rights discourse.*

No social transformation takes place in a vacuum; whatever happens is shaped by the general social context within which it happens, and which both determines and is determined by this environment. In the case of medicine, its linkage with science came about during the course of modernity and had to co-exist with all the significant features of this historical period. Therefore, it exists within a network of influences and develops only in relation to those influences.

From all the possible aspects of the network of ideas and events that constitutes modernity, the approach I am discussing is primarily inspired by *individualism*; especially by particular understandings of this notion, which have determined, to a very significant extent, fundamental perceptions of western, post-war capitalist societies.<sup>78</sup> The use of the plural here is not mistaken: the matrix of ideas that are linked with individualism belongs to a number of traditions (the most prominent of which is liberalism),<sup>79</sup> that co-determine what individualism is about. For instance, traditional notions of modernity insist on a sharp distinction between the individual and the state, whereas theories of late modernity rework this distinction in accordance with the particularities of risk society.<sup>80</sup> However, and leaving the perplexities of this debate aside, a “core” of individualism can be identified: this is the assumption that the basic unit of the social is the individual. This latter has to be understood as an autonomous agent, abstracted from any particular historical and social circumstances at the outset. From this premise, a whole edifice of ideas develops, primarily oriented to the assertion that social progress can only be achieved through individual flourishing. Consequently, the individual assumes intrinsic

<sup>78</sup> Individualism is a very complex philosophical theory, which comprises a huge variety of trends and arguments, not always coherent and non-conflicting. The relevant analysis escapes the purposes of this chapter, but a useful introduction can be found in N. Barry, *An Introduction to Modern Political Theory* (4<sup>th</sup> edition, London: MacMillan Press Ltd, 2000), pp. 11ff and in S. Aniveri and A. De-Shalit (eds.), *Communitarianism and Individualism* (Oxford: Oxford University Press, 1990). Also, very informative is the discussion of J. Rawls in his classic work *A Theory of Justice* (revised edition, Oxford: Oxford University Press, 1990).

<sup>79</sup> For an analysis of the current views on liberalism, see N. MacCormick, *Questioning Sovereignty: Law, State and Nation in the European Commonwealth* (Oxford: Oxford University Press, 1999), chapter 3.

<sup>80</sup> For further analysis, see Z. Bauman, *Liquid Modernity* (Cambridge: Polity Press, 2000), pp. 30ff.

value, her interests must be respected and her well-being within the social network is of crucial importance. What matters primarily is the individual.

Within this framework, power, and especially its concentration in specific agents, has unsurprisingly been regarded with suspicion, as it carries with it the potential of abusive use and ultimately of exploitation of individuals. The obvious reaction is that the individual must be protected from constellations of power, through a process of constant scrutiny. Since in the course of modernity the state became the major holder of power, this sensitivity was transformed into a general concern of protection against possibly abusive state activities and the primary aim was to develop mechanisms to counter state power.

Against this background, ideas emanating from the tradition of natural law and from the humanistic premises of the Enlightenment were combined with the rigid, conceptual categorisations of the codified continental legal systems and paved the way to the rise of the system of human rights.<sup>81</sup> To be more precise, the combination of the concept of a legal right (namely someone's *claim* that correlates with someone else's *duty*),<sup>82</sup> with the primary significance that the abstract individual has acquired as this has become expressed in developing humanistic values and principles, gave rise to the new concept of "universal", "human" rights. These are rights special in character, which aim at protecting the individual against the state, by designating particular areas of individual freedom, within which the state cannot interfere, or at least not without justification. That is why these rights were characterized as *negative* or *protective* rights. Yet, in the course of time this original conception of human rights developed into a much more general system, which defines the relationship between the state and the individual in its entirety and which focuses not only on the issue of protection, but also on the more general problem of the well-being of the individual, especially since in modern societies it is very much the state that co-determines the living conditions of individuals. Therefore, it is no longer the case that human rights are simply negative rights. A new generation of rights has emerged, the so-called *social* rights, in terms of which it is demanded from the state not only to abstain from interference, but also positively to act in order to enhance the

<sup>81</sup> Obviously, the length of the literature regarding the emergence of human rights is immense. For a very compact presentation, I will refer to M. Freeman, "The Philosophical Foundations of Human Rights" (1994) 16 *Human Rights Quarterly* 502. See also J. Waldron, *Theories of Rights*, (Oxford: Oxford University Press, 1984); C. Tomuschat, *Human Rights: Between Idealism and Realism* (Oxford: Oxford University Press, 2003), chapter 2; J. Donnelly, *Universal Human Rights in Theory and Practice* (London: Cornell University Press, 1989).

<sup>82</sup> I borrow this definition of a legal right by the classic analysis of W. Hohfeld, especially in *Fundamental Legal Conceptions* (New Haven, Connecticut: Yale University Press, 1923); for further analysis, see F.M. Kamm, "Rights" in J. Coleman and S. Shapiro (ed.), *The Oxford Handbook of Jurisprudence and Philosophy of Law*, (Oxford: Oxford University Press, 2002), pp. 476ff.



life conditions of individuals. This happens in a twofold way: by providing particular services to the citizens and by allowing their participation in the decision-making processes through the realisation of *political rights*, this being a third step in the gradual expansion of the human rights apparatus. Accordingly, the system of human rights consists nowadays of negative, social and political rights.<sup>83</sup>

The most important outcome of this historical expansion of human rights is that it transformed a special legal structure into a much wider system of perception of reality, quite dominant in modern societies. Human rights have become a *discourse*, namely a complete conceptual system, according to which problems are framed and reality is defined. Being a discourse, it is something beyond mere legal categories; it is expressed in a plurality of ways,<sup>84</sup> which naturally include normative provisions of even constitutional status, but also political declarations, projects of action, and, quite often, lay perceptions. Its rhetorical force is enormous; and although, its actual significance can be contested, it seems that currently almost everything is or can be recast in terms of human rights. Within such an atmosphere it is not surprising that a wide range of events has come to be understood as human rights infringements. To summarise, the modern system of human rights, originating from particular individualistic concerns, currently consists of a plurality of elements and structures, and has become a “culture” on its own,<sup>85</sup> a kind of a “vernacular language”,<sup>86</sup> which insists on protecting individuals and groups from abusive power and on cherishing positively certain fundamental, humanitarian values.

### c) Refining the human rights argument.

On the basis of the socio-political background just described, it is not difficult to see why the human rights discourse was employed to counter the advent of scientific medicine

<sup>83</sup> For the emergence of three generations of human rights, see the analysis in C. Tomuschat, 2003, chapter 3; C. Wellman, “Solidarity, the Individual and Human Rights” (2000) 22 *Human Rights Quarterly* 639 and J. Donnelly, “Human Rights, Democracy and Development” (1999) 21 *Human Rights Quarterly* 608. Also, although from a different theoretical perspective, see J. Habermas, *Legitimation Crisis* (Boston: Beacon Press, 1975).

<sup>84</sup> For an introduction to this point, see R. Beddard, *Human Rights and Europe* (Cambridge: Grotius Publications, 1993); A. Robertson and J. Merrills, *Human Rights in Europe* (Manchester: Manchester University Press, 1993); L. Betten and N. Grief, *EU Law and Human Rights* (London: Longman, 1998); T.K. Hervey and J.V. McHale, 2004, pp. 24-25.

<sup>85</sup> The idea that the system of human rights has become a particular culture, within which specific ideals are actualised has generated a very sophisticated debate regarding the ideal context of this culture, especially in the light of those rights that promote values like mutuality, interdependency, community etc. For a helpful overview, see I. Ward, “The Echo of a Sentimental Jurisprudence” (2002) 13 *Law and Critique* 107, pp. 116ff; F. Klug, *Values for a Godless Age: The Story of the United Kingdom’s New Bill of Rights* (Harmondsworth: Penguin, 2000); C. Wellman, 2000; S. Sedley, “Human Rights: A Twenty-First Century Agenda” (1995) *Public Law* 386.

<sup>86</sup> I borrow this term from M. Loughlin’s, *The Idea of Public Law* (Oxford: Oxford University Press, 2003), where it is used to describe a similar effect of the public law.

and thus to inform significantly the proposition I am discussing.<sup>87</sup> Since in the era of scientific medicine the power vested in doctors is increased, the individual patient runs a true risk of becoming a victim of exploitation and abuse. Given that the view that power in general must be scrutinised constitutes now a dominant political ideal, it follows that the power of the medical profession must also be scrutinised. That is why human rights are called upon. As the apparatus of human rights (both as a legal category and as a discourse) seem to be an efficient mechanism in countering the assimilation of abusive power and in generally enhancing the general well-being of individuals, it makes sense to maintain that the same apparatus should be the corner-stone for the regulation of medical practice, even though the “danger” here emanates not from the state directly but from a professional group. From the point of view of the doctrine, a plausible conclusion is that medical law is indeed a sub-category of human rights law.

Essentially, this conclusion can be read as a “political” claim: it endorses the tradition of liberal individualism, accepts the primacy of the interests of the individual patient, highlights the potential perils of medicalisation and provides an understanding of medical law compatible with the project of liberating patients from possible abuses, using human rights as a protective device. It is based very much on the rhetorical force of the human rights discourse and insists on a higher level of protection than the one possible according to the “ordinary” rights of private law. Also, in tune with the expansion of the human rights discourse, it goes beyond the original idea of negative rights alone and gradually takes on board social rights too. In this respect, it examines how the human rights apparatus can be fused in the context of medical practice and it does so with a twofold orientation: namely to explore how protection can be achieved within the direct interactions between doctors and patients, and also to consider how the state conditions the delivery of health services on the basis of which medical practice is essentially substantiated and direct doctor-patient interactions are very much determined.<sup>88</sup> To do so, it investigates the normative provisions that promote human rights in the particular context of health and focuses on instruments such as domestic legislation, international treaties and political declarations that promote negative and social rights.<sup>89</sup>

<sup>87</sup> This is not to say that other factors did not contribute to it: as with the previous definitional proposition, what happened during the Second World War (which significantly influenced the European Convention of Human Rights in 1950) was also immensely important.

<sup>88</sup> So, both negative and social rights are significant, although the latter function on the periphery of the main focus that remains the doctor-patient relationship with its possibilities of abusive power.

<sup>89</sup> The normative sources that relate the system of human rights with the sphere of medicine have rapidly grown. For a presentation of these sources, their provisions, and ultimately the particular rights that are significant in the context of health, see amongst others G. Annas, “The Function of Legal Rights in the Health Care Setting” in H. Engelhardt and S. Spicker (eds.), *The Law-Medicine Relation: A Philosophical Exploration* (Dordrecht: Reidel

So far, I have identified the general characteristics of the argument that medical law is a sub-category of human rights. Nevertheless, this still remains a crude statement. It seems to me that this general proposition may have two possible meanings, which in turn may establish two different versions of it. I will call the first one the *hard* version and the second the *soft* version.

Taking on board the gradual sophistication of the human rights discourse and the constant emergence of normative, legal pronouncements that directly regulate human rights issues, the hard version would take the following form: medical law would be identifiable as exactly the area of the legal system that crystallises this normative output. To be precise, medical law can be understood as the sum of human rights regulation that refers to medical scenarios; it is in essence *human rights law* as applied to medicine. This is a hard version of the proposition as it is faithful to a direct and explicit orientation to human rights law. As a result, it is a concrete and purely legal version, since it essentially refers to the legal categories that constitute medical law and to the rhetorical force of the human rights discourse. That is why in considering its plausibility it is necessary to engage in a technical, essentially legal, analysis. Accordingly, it is simultaneously a hard and narrow version of the general proposition

On the contrary, a soft version of the account would not insist so much on legal categorisations. Rather, it would focus on the system of guiding principles that the human rights discourse entails, and would highlight that this system serves as the basic conceptual component of medical law both in terms of identifying the actual problems that fall within the discipline and in terms of running across the solutions that the legal system produces. The aspirations of the human rights discourse should serve as a prevailing “ethos” for medical law,<sup>90</sup> as a guiding orientation that renders the discipline meaningful and as an organising principle of all the relevant material. This is a more conceptually-oriented version of the general proposition that is moderate in the sense that it does not limit itself only to the specific categorisations of human rights law; also, it is a wide one, since it allows for diversity and flexibility as to the precise way in which the law gives content to human rights aspirations.

In the next section, I am going to provide a critique of both these versions. All the arguments that I am going to present are significant to both of them. However, what I am calling constitutional and empirical objections are more important for the hard

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Publishing, 1978); J.M. Mann *et al.*, 1994 and T.K. Hervey and J.V. McHale, 2004, where they particularly discuss the impact of the European Convention of Human Rights and Fundamental Freedoms 1950, of the Charter of Fundamental Rights of the European Union 2000 and of the Human Rights Act 1998.

<sup>90</sup> I am borrowing the term “ethos” from the analysis in J.K. Mason and G.T. Laurie, 2005, p. 45.



version, because they primarily advance some explicitly legal and empirical considerations. By the same token, the conceptual concern refers primarily to the soft version of the account, since it challenges the conceptual background of the human rights ethos within medicine.

#### **d) The critique.**

##### *i. The constitutional objection.*

This objection originates from a particular characteristic of the human rights system, namely the fact that notwithstanding its particular content, human rights have traditionally been understood as rights against or in reference to the *state* and its agents. In this respect they describe a “vertical” relation, which includes the individual on the one hand, and the state on the other.<sup>91</sup> The constitutional objection, here, is that this verticality has to be taken seriously. Any attempt to apply the human rights apparatus in the particular context of medicine has to consider that verticality entails that the patient is to be protected against the state. This would not be problematic only if medical practice was totally within the control of the state. However, in modern western societies this is rarely the case. The reality of medical practice assumes both state related and private providers of medical services, the exact balance between the two being determined by the political, social and fiscal particularities of each country. In the UK, a mixed system is achieved through the combination of public institutions related to the NHS, which substantiates the government’s obligation to provide medical services,<sup>92</sup> with a rapidly augmenting private sector, which is comprised of a variety of agents, ranging from individual health care professionals to large private hospitals.<sup>93</sup> Leaving aside the exact structure of the whole system,<sup>94</sup> the problem remains that, because of verticality, the human rights apparatus can be involved only when a patient is treated within the framework of the NHS, since only then the state is involved. On the contrary, whenever medical services are provided within the private domain, the appeal to human rights seems to be unfounded, since there is no state involvement. Along these lines, the main

<sup>91</sup> The idea of “verticality” essentially invokes some version of a political philosophy of classical liberalism, and is also linked with individualism. For a further exploration of this point, see D. Dyzenhaus, “The New Positivists” (1989) 39 *UTLJ* 361.

<sup>92</sup> For further analysis of this point, see J. Montgomery, 2003, pp. 51-53.

<sup>93</sup> For a detailed presentation of the how the delivery of medical care is structured within the UK, see J. Montgomery, 2003, pp. 81ff, with further references.

<sup>94</sup> Especially in the UK, one can identify further perplexities, given that privatisation gradually “penetrates” the NHS. For this process, see A.M. Pollock, *NHS plc: The Privatisation of Our Health Care* (London: Verso, 2004).

constitutional objection that the human rights argument is bound to answer is the potential exclusion from the definition of medical law of all the instances of medical practice that do not involve the state.

It goes without saying that this is an over-simplified statement. It is based on the premise that human rights are only capable of vertical application and have no impact whatsoever when the private domain is involved. Although this was the traditional position, the gradual accumulation of power by private bodies and institutions has generated a tendency towards the possibility of utilising the human rights apparatus also in private, "horizontal" relations. The possibility takes the human rights system away from the citizen/state relationship and locates them to any relationship that structurally integrates the possibility of abusive power, even though it is still the state that is ultimately responsible for the protection of individuals.<sup>95</sup>

The debate regarding the horizontal application of human rights is still very acute and a range of contested options is presented. Essentially, the possibilities range from a rigid insistence on verticality<sup>96</sup> to an unqualified acceptance of horizontality,<sup>97</sup> the underlying issue being the accepted degree of preserving the integrity of the private sphere. Within these two extremes, several moderate versions of a mixture of the two have been proposed,<sup>98</sup> the most popular of which seems to be the so-called "indirect" horizontality, according to which the human rights apparatus has direct effect only in vertical relations, but can also indirectly affect horizontal relations, by providing interpretative tools and conceptual influences.<sup>99</sup> To be more precise, this idea means that the system of human rights may provide normative guidelines even for the private domain, on the premises that the law that governs private relations is applied as consistently as possible with the underlying principles of the human rights apparatus. It is exactly this assertion that captures the core of the idea of indirect horizontality.<sup>100</sup>

The significance of the need somehow to refine the rigid verticality of human rights is apparent for the legal regulation of medical practice, especially if one considers the private aspect of it. According to the approach that one endorses, the problem of

<sup>95</sup> For an introduction to the relevant debate, see A. Clapham, *Human Rights in the Private Sphere* (Oxford: Clarendon Press, 1993) and D. Friedmann and D. Barak-Erez (eds.), *Human Rights in Private Law* (Oxford: Hart Publishing, 2001).

<sup>96</sup> For this view, see in details W.P. Marshall, "Diluting Constitutional Rights" (1985) 80 *NWULRev* 558.

<sup>97</sup> For advocates of this view, see B. Slattery, "The Charter of Rights and Freedoms – Does it bind Private Persons?" (1985) 63 *CanBarRev* 148 and A.S. Butler, "Constitutional Rights in Private Litigation: A Critique and Comparative Analysis" (1993) 22 *Anglo-American Law Review* 1.

<sup>98</sup> See, in details, M. Hunt, "The 'Horizontal Effect' of the Human Rights Act" (1998) *PL* 422, at pp. 426ff.

<sup>99</sup> At this level, the argument very much approximates the soft version of the doctrinal approach I am discussing.

<sup>100</sup> In this respect, the notion of indirect horizontality is very important for the soft version of the proposition I am discussing.

excluding the private domain from the core of medical law can or cannot be solved. If one is inclined to verticality the problem is irresolvable; on the contrary, if horizontality seems more plausible, the constitutional issue can be more easily settled.

What should be kept in mind, here, is that what has been said in this section so far simply tackles a founding issue about human rights and opens a range of theoretical possibilities. Nevertheless, the actualisation of these possibilities has to be investigated in *particular* jurisdictions, in terms of their internal point view and of their particular normative and probably constitutional provisions within their legal system. So, the problem cannot be practically solved by simply choosing the most plausible idea at the theoretical level. One needs to take into account the specificities of the jurisdiction that provides human rights protection. It is at this level only that the balance between verticality and horizontality must be investigated, along with its outcome regarding the actual impact of human rights on the private sphere and, for the purposes of this thesis, on the private provision of medical services.

In the case of the legal system of the UK, the answer to the issue must be traced to the legal provisions that establish the UK human rights system. Within the particular constitutional setting of the country, these provisions are primarily to be found in the Human Rights Act 1998. The Act incorporates the European Convention of Human Rights and Fundamental Freedoms 1950 into domestic law and explicitly designates the framework of human rights protection in the UK.<sup>101</sup> The main effect of the Act is that all primary and secondary legislation must be read and given effect in a way which is compatible with convention rights (section 3(1)), and that it is unlawful for public authorities, including courts and tribunals (section 6(3)), to act incompatibly with a convention right, unless it is impossible to do so because of legislation (sections 6(1) and (2)). In this respect, the Act primarily designates an *obligation for public authorities* and provides that in the case of a *relevant* infringement, individuals can ask for judicial review of the unlawful act, provided that they are "victims", according to section 7(1).<sup>102</sup>

Regarding the problem of vertical or horizontal application of the Human Rights Act, the key concept is the notion of "public bodies" employed in section 6. This provision seems to highlight that the act is primarily concerned with vertical relations and does not allow for any direct horizontal effect. However, the absence of a definition,

<sup>101</sup> For a detailed presentation of the Act, see J. Wadham and H. Mountfield, *Blackstone's Guide to the Human Rights Act 1998* (London: Blackstone, 1999).

<sup>102</sup> Alternatively, the individual "victim" can rely on any other appropriate procedure.

within the Act, of what is to be considered as a public body<sup>103</sup> obscures the situation, especially if one considers the whole structure of the Act. As far as the context of medicine is concerned, two issues have to be explored. The first refers to the nature of the bodies within the NHS and their possible classification as public bodies. The second refers to private providers of medicine and explicitly raises the issue of the potential horizontal impact of the Act.

The first issue seems to be easily resolvable, since the idea that NHS bodies are public bodies for the purposes of the Act is widely uncontested, on the premise that they provide a public service and that they are essentially controlled by the state.<sup>104</sup> Therefore, the actions of doctors attached to the NHS in general fall within the ambit of the Act. On the contrary, the second issue is much more problematic and is informed by the general debate regarding the horizontal effect of the Human Rights Act. This debate is still in the process of framing a settled account of the exact effect of the Act, with the possibility of consensus being so far reduced only to the assertion that direct horizontality is excluded. In an attempt to summarise this debate, it can be said that the majority of arguments push forward one or another version of indirect horizontal application,<sup>105</sup> which allows, under different prerequisites, a certain expansion of the normative horizon of the Act into the domain of private relations. For instance, Murray Hunt argues<sup>106</sup> that the Act must be interpreted as applying the Convention to all law, and therefore it is not only indirectly applicable to horizontal relations, but also creates new rights directly affecting the private sphere; G. Phillipson rebuts Hunt's arguments, opting instead for a traditional indirect horizontal effect;<sup>107</sup> relevant arguments have also been presented by W. Wade,<sup>108</sup> B. Markezinis,<sup>109</sup> R. Singh<sup>110</sup> and others.

Although the academic interest on the exact effect of the Human Rights Act 1998 is still very intense, especially from the point of view of the public law scholarship it

<sup>103</sup> Instead of a definition, the Act simply provides some general guidelines in section 6(3)(b).

<sup>104</sup> See the argument in I. Kennedy and A. Grubb, 2000, p. 28, J. Montgomery, 2003, p. 11 and further, the more general analysis in N. Bamforth, "The application of the Human Rights Act 1998 to Public Authorities and Private Bodies" (1999) *CLJ* 159. However, the situation seems to become much more complicated because recent developments in the NHS point towards the gradual intensification of private contracting.

<sup>105</sup> It must be stressed here that the very notion of horizontal application is not in itself free of ambiguity. For instance, I. Leigh, in "Horizontal Rights, the Human Rights Act and Privacy: Lessons from the Commonwealth?" (1999) 48 *ICQL* 57, has identified six possible types of horizontal effect!

<sup>106</sup> In 1998, pp. 435ff.

<sup>107</sup> In "The Human Rights Act, "Horizontal Effect", and the Common Law: a Bang or a Whimper?" (1999) 62 *MLR* 824.

<sup>108</sup> See "The United Kingdom's Bill of Rights" in Hare and Forsyth (eds.), *Constitutional Reform in the United Kingdom: Practice and Principles* (Oxford: Hart Publishing, 1998).

<sup>109</sup> See "Privacy, Freedom of Expression and the Horizontal Effect of the Human Rights Bill: Lessons from Germany" (1999) 115 *Law Quarterly Review* 47.

<sup>110</sup> See "Privacy and the Media after the Human Rights Act" (1998) *EHLR* 712.

is rather surprising that the issue has been essentially neglected from the point of view of medical law scholars. Even proponents of the linkage between medical law and human rights have only marginally dealt with the issue, providing peripheral and under-developed arguments. For instance, amongst many others, Kennedy and Grubb argued<sup>111</sup> that since the courts are themselves public bodies for the purposes of the Act, they have a duty to act compatibly with the Convention; therefore, in dealing with a private provider of medical services, this *judicial obligation* would presumably lead to an unqualified application of convention rights, leaving aside the question of horizontality. It seems to me that this argument begs the question, because it is exactly the range of the impact of this judicial obligation regarding the private sphere, which is contested. Brazier has proposed an indirect solution to the problem,<sup>112</sup> by implying that patients may claim that their right to a fair trial has been infringed, if the courts refuse to redress an original claim because of the private status of the original violator. However, her argument does not really address the issue of horizontality, but simply represents a proposal for a bypass, which still remains to be tested.

This neglect in dealing essentially with the problem of horizontality, not only leaves the sphere of private medicine in darkness at the outset, but also fails to appreciate whether a version of indirect horizontality in this context would be enough to sustain the original claim, that medical law is a sub-category of human rights law, as a plausible conceptualisation. This is crucial for an additional reason: the very fact that there is not a settled answer regarding the question of the Act's horizontal impact diminishes the very possibility of providing a definition *on this basis alone*. As I argued in part (B), any definition is based on focal points and central cases. This means that at the core of any definitional proposition, its premises must be settled otherwise the proposed definition cannot be sustained. This is not the case with the problem of horizontality; thus, the contestability of the relevant views harms the relevant definition of medical law in a fundamental way.

In any case, by not taking the constitutional objection seriously, the approach I am discussing has singularly failed to consider the private aspects of medicine and their expansion. By unqualifiedly assuming that the human rights apparatus is indeed a relevant regulatory device, it has to be based on the view that medical practice is essentially controlled by the state. It was the purpose of this section to show that this

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<sup>111</sup> In 2000, pp. 28-29.

<sup>112</sup> See 2003, pp. 22-23.



presupposition is, at best, unfounded and as such, a very real problem for the identification of medical law as applied human rights law.

*ii. The empirical objection.*

The aim of this section is to bring the human rights argument down to earth and to examine whether it is really the case that the actuality of medical law is shaped by the human rights apparatus.<sup>113</sup> Especially for the strong version of the proposition this is a pragmatic necessity, since, for the claim to hold, it must be the case that patients have at their disposal *enforceable* human rights against the providers of health services and that the courts truly cherish these rights.<sup>114</sup> The issue of enforceability is of primary significance, because the initial involvement of human rights is justified exactly in terms of the actual protection that they can offer. That is why the real operation of the system is important for this conceptualisation of medical law. If the enforceability of human rights is problematic in the medical context, so is the relevant delineation of medical law.

As far as negative human rights are concerned, it seems that any view that they are actually enforced to protect patients would be implausible. The grievances of patients are usually redressed through the path of private law, within which tort law (in the form of battery and negligence) is of primary significance.<sup>115</sup> As previously mentioned, the ordinary rights of private law are essentially different from human rights and originating from the pool of private relations obey the different rationality inherent to the system of private law.<sup>116</sup> Indeed, even the quickest of glances into the principles and concepts that shape modern medical law, like consent to treatment as a defence to battery, the “best interests” test when dealing with incompetent patients, over-deference to the profession in defining what counts as best interests etc., indicates that considerations of human rights law are not significantly present. Interestingly, even when these principles are being re-assessed from a human rights perspective, they are usually deemed to be compatible

<sup>113</sup> I need to stress, here, that this section refers exclusively with what happens at the level of *domestic courts*.

<sup>114</sup> For further arguments regarding the importance of enforceability see J. Montgomery, 2003, pp. 67ff and also J. McHale, “Enforcing Health Care Rights in the English Courts” in R. Burchill, D. Harris and A. Owers (eds.), *Economic, Social and Cultural Rights: Their Implementation in the United Kingdom* (Nottingham: University of Nottingham Human Rights Law Centre, 1999).

<sup>115</sup> Even A. Grubb, one of the main proponents of the human rights argument agrees that the main vehicle in protecting the right of self-determination is the tort of battery. See his “Problems of Medical Law” in B.S. Markezinis and S.F. Deakin, *Tort Law* (4th edition, 1999).

<sup>116</sup> For the specific rationality of private law, see E. Weinrib, *The Idea of Private Law* (London: Harvard University Press, 1995).

with human rights.<sup>117</sup> This means that it is still private law that is used as the main protective “device” for patients and that the additional involvement of the human rights apparatus does not change the setting dramatically.<sup>118</sup> In turn, this is very problematic for the definitional proposition that I am discussing, since if human rights simply reinforce private law there is no reason to assume that the core of medical law must be conceptualised in accordance with them.

It may well be the case, of course, that because of the constitutional setting of the UK, which was characterised by the absence of a clear legal protection of fundamental human rights and the rather delayed incorporation of the European Convention through the Human Rights Act 1998, this is a natural state of affairs, which will gradually pave the way to a complete operationalisation of the human rights apparatus.<sup>119</sup> Nevertheless, this is not so self-evident. To begin with, it is not clear at all if the Act truly establishes enforceable rights at the disposal of individuals or even if it establishes new rights at all;<sup>120</sup> rather, as we saw, the provisions of the Act are explicitly creating a set of obligations *for the public bodies to act in accordance with the Convention*, obligations that do not correlate necessarily with directly enforceable human rights. At a further level, it is still very contested whether the Act will have a very significant actual impact in the medical context. It has been claimed that this is not the way according to which the situation is evolving and that the courts still remain reluctant in changing the principles emanating from the common law in favour of a radically different human rights approach.<sup>121</sup> For the time being, it seems that this point is correct and that the occurrence of the Act has changed very little in terms of the empirical aspect of medical jurisprudence. Of course, this is just the present state of affairs; ultimately, it is only with the passing of time that the issue will be concluded.

The lack of enforceability is even more apparent when one considers the case of social rights, which refer to the state-controlled provision of medical services. Since the main public provider of medical services in the UK is the NHS, for the human rights argument to hold it is necessary for patients to be able to claim human rights infringements and to scrutinise decisions regarding the provision of medical services. In

<sup>117</sup> For instance, see *Glass v. United Kingdom* [2004] 1 FCR 553, [2004] 1 FLR 1019, where it was held that the “best interests” principle as applied by British courts is compatible with human rights protection.

<sup>118</sup> This is not to say that nothing has changed, only that the impact of human rights law is rather limited. For more recent developments see J.K. Mason and G. Laurie, 2005, pp. 41ff.

<sup>119</sup> For this argument, see amongst others M. Brazier, 2003, p. 18 and 24ff.

<sup>120</sup> See G. Phillipson, 1999, pp. 835, 838-840, where it is argued that the Act does not create new rights, but simply adds depth to the interpretation of previously existing common-law rights.

<sup>121</sup> See G.T. Laurie, “Medical Law and Human Rights: Passing the Parcel Back to the Profession” in A. Boyle *et al.*, (eds.), *Human Rights and Scots Law*, (Oxford: Hart Publishing, 2002), pp. 244-274, and A. MacLean, “Crossing the Rubicon of the Human Rights Fery” (2001) 64 *MLR* 775.



the case of the NHS, the most common scenario of this kind is the possible complaint of a patient regarding a particular decision not to authorise a specific course of treatment, or to deny access to available treatment. To put it differently, the main question here is the possibility of scrutinising decisions regarding the allocation of resources, emanating from the administrative structure and the managerial concerns of particular health providers within the NHS.

Within this framework, again it is not some kind of human rights protection that is mobilised, but a specific legal concept emanating from public law, namely judicial review. Still, even when judicial review is used in order to challenge decisions that allocate resources, the courts are extremely reluctant to interfere with the decision-making process,<sup>122</sup> preferring to argue that this falls within the almost authoritative discretion of the provider. In effect, judicial decisions hardly interfere with the allocation of resources and relevant claims usually fail. To be more specific, the courts almost never challenge the substantial aspect of the decisions to allocate resources. Only when the patient's complaint refers to a procedural aspect of the decision-making process, there is a chance that her claim would be successful.<sup>123</sup> Accordingly, as far as social rights are concerned, it remains problematic to argue in favour of the human rights approach,<sup>124</sup> not only because, again, another legal path is frequently used, but also because the courts are not in practice willing to interfere with NHS decisions.<sup>125</sup>

To summarise, it seems that at this empirical level, the hard version of the human rights argument cannot capture the actuality of medical jurisprudence, especially in terms of enforcement of rights at the domestic courts. This being the case, the only possibility to sustain the argument is to opt for its soft version, to which I will now turn my attention.

<sup>122</sup> This was firmly established in a set of cases, involving different scenarios, the most significant of which seems to be *R v Cambridge HA, ex p. B* [1995] 2 AllER 129 (CA). For a thorough analysis of the case, see C. Ham and S. Pickard, *Tragic Choices in Health Care: The Case of Child B* (London: Kings Fund, 1998); for further case-law, see J. Montgomery, 2003, pp. 68ff.

<sup>123</sup> For a presentation of the relevant cases, see J. Montgomery, 2003, pp. 72-73.

<sup>124</sup> Unless one hopes for a political change that would influence the way courts decide cases, as Brazier, 2003, p. 29 seems to imply.

<sup>125</sup> This is a rather interesting state of affairs, because it would be expected that the bureaucratisation of the NHS structure would have led to the intensification of scrutiny of its decisions through judicial review. For this point, see I. Kennedy and A. Grubb, 2000, pp. 9ff and J. Montgomery, 2003, p. 52, 62ff and 104 where he claims that the counter tendency here is to intensify the possibility of internal accountability.

*iii. The conceptual objection.*

In this section, I will focus my attention on the conceptual premises that determine the argument that medical law is a sub-category of human rights law. In essence, I will investigate the conceptual understanding of medicine that gave rise to this argument and I will challenge some of the major assumptions regarding the nature of medicine that the argument entails. In this respect, the critique herein is more significant for the soft version of the human rights argument, since this *is* a conceptual version, based on the importance of a prevailing human rights culture.

My conceptual objections are located at three distinct levels. The first refers to the understanding of the power that doctors enjoy; the second refers to the understanding of the doctor-patient relationship in adversarial terms, which underlies the invocation of human rights; the third one refers to the institutional character of modern medicine. I will present these levels in turn, but beforehand I must insist on a crucial point, namely that they just typify problematic conceptions regarding medicine that the human rights argument has to accept in order to be plausible. It does not follow that in rebutting them, I propose a more proper conceptualisation of medicine, but rather that I intend to spell out specific conceptual misunderstandings.

To begin with, the whole human rights argument is ultimately based on the assumption that a) the power vested in doctors has to be exceptionally scrutinised because of their expert status and that b) the imbalance of power between doctors and patients is such that abusive exploitation is constantly *ante portas*. It seems to me that both these assumptions are mistaken. As to the first issue, it has been argued<sup>126</sup> that even though the power that the doctors enjoy is indeed significant, this does not lead to the conclusion that it is so beyond scrutiny that an exceptional protective device must be employed. Because of the gradual downgrading of the private and mystic character of pre-scientific medicine, of the interdependence of modern health care professionals, of the incorporation of commercial elements in the practice of medicine, which entail that the success of the profession is evaluated according to the quality of the "product" that it provides and crucially of the general intensification of science's scrutiny, modern medicine is essentially an open social field, which is already constantly monitored from a variety of perspectives. Especially the insistence on the final product, namely on the

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<sup>126</sup> Especially by J. Ladd, "Physicians and Society: Tribulation of Power and Responsibility" in H. Engelhardt and S. Spicker, (eds.), *The Law-Medicine Relation: a Philosophical Exploration* (Dordrecht: Reidel Publishing, 1978), pp. 33ff and M. Davies, 1998, pp. 19-20.

saved or cured patient, delineates a particular version of success, which is visible and easily understood by almost everyone, without the requirement of professional qualification. The conclusion is that if the practice of medicine is so scrutinised,<sup>127</sup> then it does not seem necessary to involve a particular mechanism like human rights in order to provide a specialised type of scrutiny.

As to the issue of abuse, a similar critique can be put forward. It is true that a relationship of imbalance of power exists between doctors and patients. However, this does not necessarily imply that this will result in abuse and exploitation. It may well be the case that exactly because a *power structure exists*, a particular therapeutic context becomes stabilised, with specifically defined roles and well structured expectations. Although an imbalance of power is integrated in this structure, the structure itself designs the options that are available to the parties and, in this respect, spells out alternative options, including the possibility of abuse, which is itself countered because of the internal constraints of the structure. It follows that by neutralising a set of possibilities within the doctor-patient interaction, a stable context of power and expected practice ultimately minimises the potential for abuse, at least in terms of the usual course of events.

This latter point can be better understood when linked with the second level of my conceptual concerns, namely on the delineation of the doctor-patient relationship as an adversarial one. The very tradition of human rights, especially when we consider negative rights, is based on assumptions of adversarial relationships: if this is taken into the medical context, it must mean that the doctor and the patient interact as adversaries, in the quest for different and probably conflicting interests. This repercussion for the human rights argument, in terms of which the only way out is to insist on interpreting the situation as a constellation of (patients') rights and (doctors') obligations, seems to misinterpret the actual practice of medicine as a zero sum game. This picture ignores other, equally significant aspects of the practice, namely the intimacy of the doctor-patient relationship that generates feelings of trust and collaboration<sup>128</sup> and the caring and therapeutic nature of the relationship that contradicts adversarial accounts. More importantly, it underestimates the real community of interests within which modern medical practice is better delivered, as well as the very long tradition of professional ethics that support the idea of beneficence through mutual respect and inter-

<sup>127</sup> It seems to me that the intensification of scrutiny can be easily proven, if one considers the significant rise of claims against doctors, especially in terms of civil liability.

<sup>128</sup> For the importance of trust and collaboration, see H. Teff, *Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship* (Oxford: Clarendon Press, 1994) pp. 71 and 117ff J. Ladd, 1978 and J. Katz, 2002.

dependency<sup>129</sup> and not through conflict. The fact that a professional tradition focusing on the well being of the patient is in place is crucial in realising that cooperation, interaction and in essence solidarity between doctors and patients are present, actual elements of the everyday practice of medicine. Consequently, a definition of medical law that probably unconsciously has to insist on the adversarial aspects of medical practice, fails to recognise a more general part for the law. It neglects the social positions and bonds around the practice of medicine and undermines the crucial collaborative and intimate aspects of it.<sup>130</sup>

Here, an additional point must be stated: my attack on the adversarial nature of the doctor-patient relationship is explicitly a conceptual claim. It does not deny that law is primarily oriented to the management of conflict, both in terms of regulation (which prevents conflict) and adjudication (which addresses particular conflicts); it does not even imply that the doctor-patient relationship does not generate conflicts, in terms of which the law is involved. My point is that it is problematic to make sense of this relationship as adversarial *per se*, at a conceptual outset. This would be a conceptual mistake, which would obscure both the actuality of the relationship as previously described and the exact nature of the possible conflicts that this non-adversarial (again, at the *conceptual* level) setting may produce.

At a final conceptual level, the human rights argument fails to recognise that the doctor-patient relationship does not exist in a vacuum, but rather in a specific *institutional* and *administrative* dimension. J. Montgomery has plausibly argued<sup>131</sup> that modern medicine takes place usually in the complicated environment of the modern hospital, which is shaped by a variety of considerations, being substantially more complex and subtle than any face-to-face interaction. It is an environment that integrates professional competence, administrative decision-making, financial distribution of resources, political ideals etc. This complicated environment must be integrated into any conceptual account of medicine, and ultimately, of medical law. At a further level of analysis, this institutional dimension must also be taken into account when the organisation of the medical profession is concerned. The doctors are not simply competent individuals that exercise skill in particular cases, but members of an institutionalised profession.<sup>132</sup> Therefore, they

<sup>129</sup> See A.V. Campbell, "Dependency: the foundational value in medical ethics" in K. Fulford *et al.* (eds), *Medicine and Moral Reasoning* (Cambridge: Cambridge University Press, 1994), pp. 184-192.

<sup>130</sup> For a much more expanded presentation of this line of thinking see, amongst others, A. McCall-Smith, 1997 and D. Morgan, 2001, pp. 8-9.

<sup>131</sup> See J. Montgomery, 2003, *passim*.

<sup>132</sup> For an elaborate presentation of this point, see U. Beck, *Risk Society: Towards a New Modernity* (London: Sage, 1992), pp. 208ff.

operate in accordance with the institutional setting of their professional affiliation and carry with them all the features of this setting.<sup>133</sup> As a result, any attempt to define medical law would require one to evade the narrow scope of the direct interaction between doctors and patients and to investigate seriously the institutional dimension of medical practice, even when the focus remains on the emergent culture of human rights.

To summarise these points, I am arguing that even at the conceptual level, the human rights argument has either misinterpreted or failed to take into account several crucial aspects of the actuality of modern medicine. Adding this to the constitutional and empirical objections previously presented, it seems to me that this proposition also provides an implausible account of the subject matter of medical law.

## D. Conclusion.

The aim of this chapter was to identify and evaluate the main doctrinal propositions regarding the subject matter of medical law. In the course of the analysis, two such ideas were presented: both deemed unsatisfactory, even in terms of their own underlying premises. The first, which identifies as the subject matter of medical law its orientation to the domain of medical ethics, is problematic on the basis that it misrepresents medicine in a conceptual level (by overstressing the significance of medical ethics and by being under-inclusive in terms of other aspects of medicine), and that it underestimates the jurisprudential problems of linking law with ethics. The second, which prefers to perceive medical law as a sub-category of human rights law, has also been discarded for a variety of reasons, which include the complexity of the fundamental constitutional problem of applying human rights in horizontal relations, the rather limited significance of human rights in terms of the actuality of medical jurisprudence (especially considering the question of enforcement) and more importantly the conceptual misrepresentation of several significant aspects of modern medicine.

Of course, by arguing that these propositions are unsuccessful in delineating plausibly the discipline of medical law, I do not imply that they are unnecessary or insignificant. On the contrary, they do highlight crucial issues regarding the link between law and medicine and their very existence contributes to the particular substantiation of this link, since *they shape the understanding of several issues*. Nevertheless, their failings in achieving the aim of a plausible conceptualisation, is crucial for my own project, for an

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<sup>133</sup> I will come back to this point in the next chapter of the thesis.



obvious reason. By discarding them, I am arguing that the orientation of law to medicine is not substantiated according to them and, thus, the question of how the discipline is constituted remains open.

This being the case, the next step of my project is to continue with the “unpacking” of the discipline, and to have a very close look at the empirical reality of medical law, namely at the legal norms that operate within the body of the discipline. So, in the next chapter I will examine how the law has so far registered the orientation of law towards medicine, in terms of actual legal practice. In anticipation of what will be said, I can already hint that this discussion will expose a domain of *complexity*, which is of course intensified by the presence and the impact of the definitional propositions discussed in this chapter. The notion of complexity will be of crucial importance and will guide the analysis of the subsequent chapters of the thesis, since it would have to be theoretically reassessed later on. For the time being though, let me leave this as a pending question: the norms that belong to medical law have important lessons to teach us regarding the constitution of the discipline.



## **Chapter 2**

### **The Empirical Complexity Of Medical Law**



## A. Introduction.

Having focused extensively on the doctrinal propositions in the previous chapter, I turn my attention here to a different line of enquiry. In this chapter, I take into consideration the existing empirical “data” of medical law and I will investigate what they reveal for the constitution of the discipline. It should not come as a surprise that this empirical aspect merits a detailed discussion in its own right: especially during the last 30-odd years, the law has dealt with many issues emanating from the sphere of medicine and arguably its intervention is still expanding. In the beginning of the 21<sup>st</sup> century, it can be said confidently that the urgent call of Ian Kennedy in the early 80s,<sup>1</sup> for the need to legally scrutinise medicine has been truly heard: the law has *actually* intervened. As a result, there exists now a large body of legal material that constitutes the empirical aspect of the link between law and medicine.

Although it would be theoretically puzzling to ask what one means by the term “empirical” or “raw” legal material,<sup>2</sup> in this chapter I take this to refer to *legal norms*, whatever their possible source. To put it more accurately, I intend to take into account both *legislation* and *adjudication* as the two terrains within which the legal regulation of medicine is carried forward through the generation of legal norms. A fundamental postulation here is that the orientation of law towards medicine should not be understood solely either in terms of parliamentary or governmental initiatives or in terms of judicial interventions triggered by litigation of any sort. Rather, I insist that legal regulation originates from both and thus that any relevant enquiry must take both into consideration,<sup>3</sup> especially since they seem to coexist in a context of mutual influence and co-development.

In discussing the empirical material, the character of this chapter is mainly *descriptive*. In what follows, I do not intend to criticise the legal position, to distinguish between right and wrong legal arguments and to provide normative proposals regarding what the proper legal answers should be. Instead, I will present the empirical data as only a marker of how the law has dealt so far with medicine. In addition, what I am about to embark on is not a detailed examination of the totality of the extant legal regulation of

<sup>1</sup> See especially I. Kennedy, *The Unmasking of Medicine* (London: Allen and Unwin, 1981).

<sup>2</sup> I borrow the term “raw” from N. McCormick’s, *Rhetoric and the Rule of Law: a Theory of Legal Reasoning* (Oxford: Oxford University Press, 2005), p. 29.

<sup>3</sup> Of course, this is not to say that there are no differences between legislation and adjudication. For a very thorough discussion of the issue, see D. Kennedy, *A Critique of Adjudication {fin de siècle}* (Cambridge, Massachusetts: Harvard University Press, 1997), especially chapters 1&2 where he introduces the main themes of the relevant debate.

medicine, but a much more modest presentation of only some of its main themes.<sup>4</sup> To provide a further caveat, what follows refers almost exclusively to the UK jurisprudence, with a particular emphasis on English law. The reason for this choice is that a presentation as confined as mine is bound to focus only on the most significant issues and the sheer quantity of English regulation guarantees that this is the easiest source in unearthing them. This is not to say that I will totally ignore the Scottish position or the impact of EU legislation, but that I will refer to them only when this is necessary for a clearer understanding of the wider picture.

A final introductory point is also necessary. Although the perspective of this chapter is descriptive, I still need to select somehow the data that I will present. As I discussed at length in the previous chapter, any description is based on a selection process, in terms of which what counts as relevant is established. Given the complicated nature of the field I am about to explore (as this will be revealed in the course of the analysis), I need to start by discussing the premises of my own selection. I will perform this task, briefly, in the following section of this chapter (section **B**). Nonetheless, what I have to stress in advance is that my claims as to what empirical data are relevant should not be understood as an attempt to provide another doctrinal theory. In justifying my selection, I am not implying anything about the possibility of framing these data as a unified whole. Naturally, general principles and tendencies can be identified in the selected framework and since this is the case, one could be tempted to use them as guiding orientations for doctrinal purposes. Yet, this would require an analysis of a different order and this is not what I intend to do here. To put it more succinctly, my claim refers only to the identification of some basic criteria of relevance. The arguments of the next section amount to a moderate, non-doctrinal statement that serves a simple aim: this is to delineate the scope of my empirical inquiry by locating the basic normative “space” within which the link between law and medicine can be detected.<sup>5</sup>

From then on, the structure of the chapter is rather simple. In section (**C**), I will present the relevant legal norms, based on a broad distinction between case law and legislation.<sup>6</sup> Then, in section (**D**), I will focus on the judicial terrain and explore the

<sup>4</sup> In this respect, I admit that I am liable to the criticism of arbitrariness; yet, I hope that my presentation covers the material in a satisfactory manner.

<sup>5</sup> This kind of basic, “pre-doctrinal” delineation is similar to what Ronald Dworkin has described as the “preinterpretative stage” in any attempt to interpret a social phenomenon. At this stage, the only thing that happens is exactly a basic selection of the admittedly very tentative content of the phenomenon under investigation. It seems to me that this thesis stands even outside the premises of Dworkin’s theory of constructive interpretation. For further analysis, see his *Law’s Empire* (Oxford: Hart Publishing, 1986), pp. 65-66.

<sup>6</sup> Let me stress that I am employing this distinction in order to structurally simplify the presentation of the relevant legal norms. Therefore when discussing the common law, I will occasionally refer to legislation that expands or

modality of reasoning that the courts use when dealing with the relevant cases. Having completed this exploration, the concluding section will assess what can be inferred from the empirical legal data. This assessment will then be used in order to introduce the theoretical analysis, which will be pursued in the next chapter of the thesis.

## **B. The selection of the relevant material.**

Given that the general context of my thesis is the orientation of law to medicine, one would assume that what counts as relevant ultimately depends on my understanding of the notion of medicine. This is indeed true: the normative material that I will discuss in the subsequent sections has been selected on this basis. Yet, although it is tempting to conclude the discussion of relevance with this bold statement, the situation is not as clear-cut as it seems. The main problem is that the concept of medicine is not free from ambiguity and contestability. Therefore, I am obliged to justify my selection of the relevant material by clarifying what the term “medicine” may entail.<sup>7</sup>

The ambiguities regarding the notion of medicine, spring from its essentially social character. Medicine is a social phenomenon that allows for different interpretations and that generates a set of complicated questions. Is it a social practice or a social institution? Is it accurate to perceive it as just a matter of technical skill? Should it be understood as a domain of applied scientific knowledge? What are its purposes and its societal functions? How does it relate with those notions that are closely associated with it, namely health, illness and disease, especially since these are themselves quite contested?<sup>8</sup> All these are significant issues that can be tackled according to a variety of perspectives. Nevertheless, against this complicated framework there seems to exist a kind of consensus, most easily identified in the use of the term “medicine” in ordinary language. Naturally, one cannot hope for a comprehensive definition there, but still a crude but popular delineation can be found along the following lines: medicine is what a doctor practises when treating a patient.

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modifies the position; similarly, when examining the statutory provisions, I will refer to the case law that interprets them, if this is necessary.

<sup>7</sup> I must warn the reader that the discussion of medicine in this section is effectively preliminary and that the underlying assumption that the law “refers” to medicine is not self-evident as such. I will revisit both these issues from a fresh theoretical perspective in the next chapters of the thesis.

<sup>8</sup> For a discussion of the ambiguity regarding these notions the reader is referred to the previous chapter.

In my view, this “lay” understanding of medicine provides a crucial insight that has to be further pursued.<sup>9</sup> What it shows is that medicine is inherently linked with a particular profession the members of which are identified as “doctors”. This linkage, obvious as it appears, has important consequences, especially when understood from a perspective focusing on the power of the medical profession. I discussed this issue in the previous chapter, where I mainly referred to the power located within the doctor-patient relationship. Nevertheless, a crucial aspect of professional power is the general status that a profession enjoys within the societal structure. This status is not something given. Rather, it is the outcome of an on-going process of competition and negotiation primarily between different professions, but also between professions, the state and other groups that have relevant, significant interests.<sup>10</sup> In the quest for societal status, several different strategies may be employed, all of which aim at consolidating professional power.<sup>11</sup> For the purposes of my present argument, the most significant of these strategies is the securing of a particular area of practice, within which a profession acquires a dominant position. Since this is the result of a struggle, it can be seen as a kind of societal “victory”, which is meaningful in the sense that the victorious profession occupies the area at stake in as total a way as possible. The area becomes its own “jurisdiction”:<sup>12</sup> *it is a domain that is delineated as “belonging” to a profession, that is defined in accordance to the way that the profession perceives itself and its practice and that has to be protected against attempts from other professions (or more generally other societal groups) to claim it for themselves.* This latter assertion implies that even a consolidated professional jurisdiction<sup>13</sup> is never unchallenged. On the contrary, it is quite possible that what has been achieved may be again open to challenge. Shifts in the exact delineation of jurisdictions are possible; equally possible and probably more significant are shifts on the particular profession or group that occupies the dominant position within a given jurisdiction. Nonetheless, in a

<sup>9</sup> Effectively, I am using here this lay understanding of medicine as a “common place” or “topos” that sustains the argument that I am about to develop. For a theoretical backing of such a methodology, see N. MacCormick (2005), pp. 17ff. with further references.

<sup>10</sup> The more comprehensive exploration of the idea that the professions are in a constant state of negotiation with their institutional environment in their attempt to achieve higher societal status can be found in M.S. Larson, *The Rise of Professionalism: A Sociological Analysis* (London: University of California Press, 1977). In this work, the author conceptualises this as an essential part of the so-called “professional project”, namely the social process through which a group becomes a profession and ultimately consolidates a privileged position within a society.

<sup>11</sup> For the strategies that the medical profession employs in its attempt to solidify professional hegemony the reader is referred to the pertinent analysis in chapter 1.

<sup>12</sup> For the notion of “jurisdiction” as an analytical tool crucial in understanding the social status and the power of professions, see A. Abbott, *The System of the Professions* (London: University of Chicago Press, 1988).

<sup>13</sup> Let me add here that this consolidation is often guaranteed through the intervention of the state that grants substantial privileges to particular professions regarding concrete areas of practice. For an analysis of this intimate relationship between the professions and the state, see T.C. Halliday, *Beyond Monopoly* (Chicago: University of Chicago Press, 1987) and K.M. MacDonald, *The Sociology of the Professions* (London: Sage, 1995), pp. 100ff. and especially pp. 105-107 regarding medicine in particular.



particular moment in time,<sup>14</sup> one can observe the state of affairs and reach a conclusion regarding what is the jurisdiction of a profession, how this is defined and what are the possible external threats.

Within these lines my claim is that medicine is the concept that denotes the jurisdiction of the medical profession; it is the domain that a particular profession has managed to secure for itself in almost exclusive terms. This statement does not entail a tautology: I do not imply that medicine should be understood through the profession and that simultaneously the profession is defined through medicine, the latter being its area of practice. On the contrary, what I am claiming is that medicine is a concept that makes sense only through a professional perspective. This is part of the very concept of the jurisdiction, which is not only secured but also *defined* and *conceptualised* by the profession that acquires monopoly in an area of practice: in addition to delineation, jurisdictions integrate a *discursive element*, in terms of which they make sense as meaningful domains of practice.<sup>15</sup> This discursive element depends on the paradigm that is currently determinative of the profession's perception of itself and its practice. Since in modern, Western societies, this paradigm is based on the *mechanical model of health*, the medical profession perceives itself as a community of experts that restore the proper function of the human body, using allopathetic techniques and based on scientific knowledge. It follows that medicine is the domain of practice within which this particular professional paradigm is actualised, since medical practice is perceived exactly in reference to this paradigm.<sup>16</sup>

<sup>14</sup> I borrow the idea that a social phenomenon can be meaningfully analysed as it stands in a particular moment in time, by Joseph Raz in his *The Concept of Legal System: An Introduction to the Theory of Legal System* (Oxford: Clarendon Press, 1970), pp. 34-35, where he argues that the legal system can be described as a *momentary system*, namely as it exists in a certain moment. I see no reason why a professional jurisdiction like medicine cannot be similarly analysed, especially if one considers a moment in time in a *broad* or *thick* sense, namely as something that captures an extended perception of what is meant by "present". For a thorough analysis of this interesting point, see N. McCormick, 2005, pp. 215-219 with further references to the relevant literature.

<sup>15</sup> This idea can be further supported by findings in organisational theory, especially if one takes into account the organisational dimensions of the medical profession (for instance the existence of the General Medical Council and the British Medical Association). From this perspective, it has been argued that organisations determine the institutional environment within which they operate. For a classic exposition of this insight, see J.W. Meyer and B. Rowan, "Institutionalized Organizations: Formal Structure as Myth and Ceremony" (1977) 83(2) *American Journal of Sociology* 340, pp. 347-348.

<sup>16</sup> One could go a step further and add that as soon as a jurisdiction is established, then it starts to produce discursive "feedback" that in turn further sustains the way that a profession sees itself. In such a way, a process of mutual influence is in place, which can be depicted as a cyclical discursive channel between a profession and its jurisdiction. An analysis of the feedback aspect is particularly useful when one focuses on how the members of a profession perceive themselves and what they are doing. Relevant research has shown that individuals develop a "working personality" that is determined by the professional practice within which they find themselves. This research has classically focused on policemen (see J.H. Skolnick, *Justice Without Trial: Law Enforcement in Democratic Society* (2<sup>nd</sup> edition, New York: John Wiley & Sons, 1975, chapter 3) and professional soldiers (see M. Janowitz, *The Professional Soldier: A Social and Political Portrait* (New York: The Free Press of Glencoe, 1964, p. 175), but its findings can similarly apply to doctors.

The idea that the discursive content of medicine as jurisdiction is determined by the currently dominant paradigm of the medical profession has two important consequences. *First*, it shows that jurisdictional shifts in the exact balance of power between different professions and groups do not necessarily change the way that a jurisdiction is conceptually defined. For instance, it is arguably the case that the monopoly of the medical profession on its jurisdiction is currently under attack.<sup>17</sup> Just to provide a few examples, other health-related professions have enhanced their position; the authority of professional expertise is challenged through the gradual appreciation of the importance of patients' choice; commercial entities and, crucially, pharmaceutical companies have an increasing impact on the direction of modern medicine. Additionally, even the negotiated terms between the medical profession and the state are in a state of constant flux, in accordance with shifts in governmental policies that generate different schemes for the regulation of the medical profession. Yet, these jurisdictional shifts do not necessarily challenge how medicine as jurisdiction is defined: they mirror the exact power position of different groups,<sup>18</sup> but they all happen against a rather stable conceptual background regarding what medicine is. In this sense, the discursive element of the jurisdiction lingers in time and integrates shifts at the level of group positioning.<sup>19</sup> This is why it is still the case that the perception of medicine remains defined by the medical profession, even if the latter's monopoly is under threat.<sup>20</sup>

The *second* consequence is that the dominant paradigm allows us to make a distinction that is crucial for understanding the regulation of medicine. Since doctors treat patients with the aim to restore their proper natural state (at least in terms of what can realistically be achieved), it follows that the jurisdiction refers essentially to the *care* of the patient, as this is manifested in the direct doctor-patient relationship that comes into

<sup>17</sup> For a detailed presentation of the reasons why this may be so, see J. Le Fanu, *The Rise and Fall of Modern Medicine* (London: Abacus, 1999).

<sup>18</sup> This list of examples regarding possible jurisdictional shifts is based on the idea that currently within medicine there exist three distinct structural interests that are represented by different groups: the "dominant interest", primarily represented by the medical profession against other professional groups; the "corporate rationalisers' interest", which is represented by the state and by managers of health care provision; the "community interest", which is represented by several groups that, for instance, may advocate patients' rights. All these groups attempt to enhance their control over the jurisdiction. For further analysis of this classification (which can be expanded through the incorporation of market interests), see R. Alford, *Health Care Politics* (Chicago: University of Chicago Press, 1975) and N. North, "Alford Revisited: The Professional Monopolisers, Corporate Rationalisers, Community and Markets" (1995) 23(2) *Policy and Politics* 115.

<sup>19</sup> Naturally, radical shifts on the identity and the positioning of the groups that control a jurisdiction ultimately influence its discursive aspect; however, for a discursive change to occur, the outcome of shifts has to be stable for a significant period of time.

<sup>20</sup> Similarly, it has been argued that although ostensibly the monopoly of the medical profession is dampening down, it remains the case that the public still trust the profession and that its authority is in fact very significant. For this line of argument, see R. Baggott, *Health and Health Care in Britain* (3<sup>rd</sup> edition, New York: Palgrave, MacMillan, 2004), pp. 235-239. For further arguments in favor of the claim that medical power remains intact, see B. Salter, *Medical Regulation and Public Trust: An International Review* (London: King's Fund, 2000).



existence because of a particular medical condition. Of course this is not a simple relationship: within its remit, several expectations develop that refer to a cluster of issues, like accurate diagnosis, successful treatment, confidentiality, meaningful communication etc.<sup>21</sup> Leaving this complexity aside, the paradigm demands that this is the primary dimension of medicine, since it is in this dimension that the aim of the profession becomes actualised. To simplify matters, from now on I will refer to this as the “technical” dimension of medicine. Nevertheless, care does not happen in vacuum. Its environment is important, since the fulfilment of the relevant expectations depends not only on the skill of the doctor, but also on a set of conditions that are determined by external factors. It is not difficult to explain why this is so: a doctor will need the help of other professionals; she will need drugs of a certain quality and therapeutic potential; what she can do is limited by the particular resources that are at her disposal in a particular hospital etc. At a more abstract level, care is influenced by the general availability of doctors, the public or private source of funding for particular treatments, the quality of medical education, the general level of scientific knowledge, the willingness of the patient to follow instructions etc. Ultimately, all these factors are determined by the particular arrangement of the provision of health services within a given society. Effectively, these arrangements are embedded into the jurisdiction of medicine by constituting its underlying conditions. From now on, I am going to refer to them as the “institutional” dimension of medicine. My argument is that this dimension is equally important in identifying how medicine is actually practised in a given society.

Within these lines, *the legal norms that are relevant to my project refer both to the technical and the institutional dimensions of medicine.*<sup>22</sup> This is admittedly a very wide statement, especially because the institutional dimension is very open-ended, being determined by a plurality of factors, the exact impact of which is difficult to measure. Yet, an understanding of the orientation of law towards medicine only in terms of its technical dimension would neglect the major practical importance of the institutional dimension. Accordingly, in what follows I will take both dimensions into account and I will present the legal norms that are apposite to both. I have already said that my presentation is based on a broad distinction between common law and legislative provisions. I can now complete this statement, by saying that the common law provisions seem to be more

<sup>21</sup> The exact content of the expectations that develop within the doctor-patient relationship can be explained as the result of the power struggles between different groups of healers in the history of medicine. For this point, see in details J. Katz, *The Silent World of Doctor and Patient* (London: Johns Hopkins University Press, 2002, first published in 1984), pp. 30ff.

<sup>22</sup> The importance of the distinction between these two dimensions is not exhausted here; I will revisit the issue on the last chapter of my thesis.

pertinent to the technical aspect of medicine (by generally regulating the doctor-patient relationship), while legislation refers both to the technical and the institutional aspect (by regulating the management of specific conditions or categories of care and by establishing a general framework of health care provision, within which medicine is practiced).

Having established in such a way the relevant empirical data let me now turn to their substantial analysis.

## C. The normative content of medical law.

### 1) Case law.

#### a) Consent to treatment.

The concept of consent to treatment probably represents the corner stone of modern medical law. As a legal norm, it embodies the principle that it is prohibited for any person to interfere with the bodily integrity of another without consent, even if this interference is of the slightest possible degree – in essence, mere touching is unlawful without consent. In the absence of consent, the tort of battery is committed and damages can be recovered. Given the usual intrusive character of medical procedures of any sort, it is unsurprising that their lawfulness is based on the consent of the patient.<sup>23</sup> Accordingly, the primary legal function of consent is to provide a defence against the tort of battery,<sup>24</sup> by negating the possibility of a doctor being held liable. Consent can be explicit or tacit and although its exact content may occasionally be a source of ambiguity,<sup>25</sup> there is no doubt that a medical procedure without consent is generally illegal.

<sup>23</sup> This has been firmly established for many decades now. For a clear expression of the rule, see *A-G's Reference (No. 6 of 1980)* [1981] QB 715, [1981] 2 All ER 1057.

<sup>24</sup> It does not follow from this that consent can always provide a defence. Crucially, one cannot normally consent to an activity that may result to a serious injury, as it has been established in *R v. Brown* [1994] 1 AC 212, [1993] 2 All ER 75. More particularly, within the medical context Jonathan Montgomery has argued that policy reasons demand that consent cannot function as a defence in a number of scenarios that include female circumcision, euthanasia etc. For this point see J. Montgomery, *Health Care Law* (2<sup>nd</sup> edition, Oxford: Oxford University Press, 2003), p. 232. Relevant provisions are included in several statutes as the Tattooing of Minors Act 1969, the Prohibition of Female Circumcision Act 1985 etc.

<sup>25</sup> It is possible that during an operation an additional medical condition is revealed that requires prompt action to be taken. In this situation, it is unclear whether an initial, general consent renders the treatment of the additional condition lawful. For an exploration of the problem, see J.K. Mason and G.T. Laurie, *Mason & McCall Smith's Law and Medical Ethics* (7<sup>th</sup> edition, Oxford: Oxford University Press, 2005), pp. 351-353, with many references to the relevant case law and pp. 386ff. where the particular case of consent to HIV testing is analysed in details.

In order to understand the legal subtleties regarding the concept of consent, one has to keep in mind the inherent link between consent and autonomy. In effect, it is this link that provides the justification for the legal requirement of consent. The patient has to consent, because she is viewed as an autonomous agent, who is able to know what is best for herself and, crucially, to make decisions about what should happen. This understanding reveals that consent is an expression of the decision-making ability of the patient, who exercises her autonomy exactly through consent. From this it follows that the decisions of patients must be respected. If the patient consents, a medical procedure can proceed; if the patient refuses, this refusal must also be respected and the doctors are not allowed to operate, even if they believe that this would have detrimental effects for the health of the patient.<sup>26</sup> Accordingly it is not only consent to treatment that is legally important; refusal to treatment is of equal legal significance.<sup>27</sup>

The link between consent and autonomy, as exemplified through a process of decision-making reveals that this general normative edifice works only if the patient is indeed an autonomous agent. What if, for any reason, she is not? Logic requires that in this case, the defence of consent is inapplicable, since it would not make sense to insist on a notion that expresses autonomy, when autonomy itself is absent.<sup>28</sup> In legal terms, this issue is problematised as the patient's *capacity* to consent, an additional concept that further elaborates the link between consent and autonomy.<sup>29</sup> Accordingly, it is necessary to develop a legal test in terms of which capacity can be assessed. Such a test has indeed been developed, but in order to discuss it meaningfully one has to distinguish between adult and minor patients.

In the case of adult patients, the law treats capacity as a relative concept. One is not capable or incapable in general, but rather capable or incapable with reference to a particular situation that gives rise to a particular decision-making process. This implies that capacity is a matter of degree and that it is much more possible for someone to be

<sup>26</sup> In support of this view see the very poignant reasoning in *Re B (adult: refusal of medical treatment)* (2002) 65 BMLR 149, [2002] 2 All ER 449.

<sup>27</sup> An opposite conclusion would be compatible with the ethos of paternalism, which is no longer prevalent in medical practice, at least ostensibly. For an elaboration of the concept of paternalism, see C. Cluvert and B. Gert, *Philosophy in Medicine* (Oxford: Oxford University Press, 1982), pp. 126ff., G. Dworkin, "Paternalism" (1972) 56 *The Monist* 64 and H. Teff, *Reasonable Care: Legal Perspectives of the Doctor-Patient Relationship* (Oxford: Clarendon Press, 1994), pp. 69ff.

<sup>28</sup> In my view the most clear presentation of this thesis in the form of an argument in front of a court of law, can be found in *Freeman v. Home Office (No. 2)* [1984] QB 524, [1984] 1 All ER 1036. There, a prisoner argued that exactly because the prison environment is structured on the basis that the autonomy of prisoners is diminished consent to treatment is no longer an appropriate concept in determining the legality of medical interventions. Although his claim failed, the argument reveals the substantial link between consent and autonomy.

<sup>29</sup> For a very detailed exploration of the notion of capacity to consent, see I. Kennedy and A. Grubb, *Medical Law* (3<sup>rd</sup> edition, London: Butterworths, 2000), pp. 596ff. and M. Gunn, "The Meaning of Incapacity" (1994) 2 *Medical Law Review* 8.

capable of making a simple decision than a complicated one. Within these lines, the test for assessing capacity has been laid down in *Re C*,<sup>30</sup> where it is provided that a patient is capable to decide when he is able to comprehend and retain information, believe it and weigh it in balancing other relevant considerations. This formulation reaffirms and further elaborates previous case law<sup>31</sup> and establishes capacity as a presumption that can be rebutted only when the test is not met. Additionally, it is completely in tune with the definitions of incapacity that are included in the recent statutes that regulate several issues regarding incapacitated adults, namely the Mental Capacity Act 2005 (s 2) and the Adults with Incapacity (Scotland) Act 2000 (s 1(6)).

Although the test in *Re C* seems to establish comprehensive criteria regarding capacity,<sup>32</sup> its practical application has not been free of ambiguity and this has led to some interesting results. Not surprisingly, the proposed test has itself been tested in situations regarding refusals of treatment, especially when doctors feel that non-treatment damages the health of the patient. Given that the refusal of a competent patient must be respected and that it is the doctors that assess the capacity of the patients, the only possible "by-pass" is to argue that the patient is incapable to consent. In a number of cases this argument was presented and quite often it has been successful. Even though the relevant case law cannot be exhaustively presented here, it seems that the courts are often reluctant to assure the validity of refusals emanating from particular religious beliefs. Especially in the case of Jehoba witnesses (a faith that essentially prohibits blood transfusions), this tendency has been widely manifested. For instance, in the previously referred *Re T*,<sup>33</sup> where the test itself was initially laid down, the court concluded that the patient's original refusal of blood transfusion should not be respected, on the twin bases that it was caused by the *undue influence*<sup>34</sup> of a third party (her mother) and that it could not refer to the deterioration of her situation that occurred as time gradually passed. Similar outcomes were reached in *Re S*<sup>35</sup> and in *Norfolk and Norwich Healthcare (NHS) Trust v. W.*<sup>36</sup> Additionally, a tendency to overcome refusals on the basis

<sup>30</sup> *Re C (adult: refusal of medical treatment)* [1994] 1 All ER 819, (1993) 15 BMLR 77.

<sup>31</sup> More importantly, the previous formulation in *Re T (adult) (refusal of medical treatment)* [1992] 4 All ER 649, (1992) 9 BMLR 46, CA.

<sup>32</sup> For a critical perspective focusing on the vagueness of these criteria, see J.K. Mason and G.T. Laurie, 2005, pp. 376-377, A. Grubb, "Commentary" (1994) 2 *Medical Law Review* 92 and M. Stauch, "Rationality and the Refusal of Medical Treatment: A Critique of the Recent Approach of the English Courts" (1995) 21 *Journal of Medical Ethics* 162.

<sup>33</sup> This case referred to a pregnant woman that signed a refusal to receiving blood transfusion after being involved in a car accident.

<sup>34</sup> For further analysis of the concept of "undue influence", see *Centre for Reproductive Medicine v. U* (2002) 65 BMLR 92, [2002] Lloyd's Rep Med 93.

<sup>35</sup> *Re S (adult: refusal of medical treatment)* [1992] 4 All ER 671, (1992) 9 BMLR 69.

<sup>36</sup> [1996] 2 FLR 613, (1996) 34 BMLR 16.



of incapacity can be detected in several cases involved pregnant women in general. There, incapacity is established on the basis of the mental state of the woman (for instance, in *Re MB*<sup>37</sup> an assessment of incapacity was justified in terms of needle-phobia), although the importance of the refusal of the competent patient is constantly re-stated and there is no doubt that in the potential conflict between maternal and foetal interests, only the wishes of the mother are to be protected. What can be inferred from these cases is that the reluctance of the doctors to affirm the capacity of patients who reach irrational decisions (at least from a clinical perspective) is often sanctioned by the courts,<sup>38</sup> even though the relevant rhetoric insists on a strong presumption in favour of competence.<sup>39</sup>

When it comes to minor patients<sup>40</sup> the situation is somewhat different. To begin with, the presumption in favour of capacity is reversed: a minor is not presumed competent to decide unless proved otherwise. Accordingly, the consent of the minor cannot function as a defence and some other way must be found to render a medical intervention lawful. Medical treatment usually proceeds on the basis of consent given by the parents. However, this consent (often depicted under the term “proxy” consent) is not as determinative as the consent of a competent adult. In some scenarios, it may be the case that parental consent is not enough for rendering an operation lawful.<sup>41</sup> Also, it is conceivable that a parent may refuse to give consent. In both scenarios, a proposed medical intervention would have to be justified in a different way: the alternative possibilities constitute the subject matter of the subsequent section. Here, I will focus my attention only to a particular complication that has emerged by the concept of the so-called “mature minor”. Let us see in some detail what this concept entails.

In the notorious *Gillick v. West Norfolk and Wisbech Area Health Authority*,<sup>42</sup> it was decided that a doctor was allowed to provide contraceptives to a girl under the age of 16, without previously informing her parents. The decision was based on the principle that a child below the age of 16 can give valid consent to treatment, provided that she is mature enough to understand fully the implications of what is proposed.<sup>43</sup> This would be of

<sup>37</sup> *Re MB (an adult: medical treatment)* [1997] 8 Med LR 217, (1997) 38 BMLR 175, CA.

<sup>38</sup> An attempt to solve the collateral problem of whether (and under what conditions) the doctors should refer their assessment of a patient's capacity to a court, can be found in *St George's Healthcare NHS Trust v. S (Guidelines)*, *R v. Collins, ex p S (No. 2)* [1999] Fam 26, (1998) 44 BMLR 194, where detailed guidelines are provided by the Court of Appeal.

<sup>39</sup> In this section, I am interested only on the problem of consent to treatment; that is why I do not discuss the basis on which these cases were ultimately decided. This is the subject matter of the following section.

<sup>40</sup> For the purposes of this section, a minor should be understood as an individual under the age of 16, according to the Family Law Reform Act 1969, s 8(1) and the Age of Legal Capacity (Scotland) Act 1991, s 2(4).

<sup>41</sup> For an introduction to the issue, see J. Montgomery, 2003, pp. 302-303.

<sup>42</sup> [1986] AC 112, [1985] 3 All ER 402, HL.

<sup>43</sup> For a detailed presentation of all the aspects of this decision, see G. Williams, “The Gillick Saga” (1985) 135 *NLJ* 1156.

course a question of fact, but it is conceivable that a minor can reach the required level of maturity (which will very much depend on the nature of the treatment proposed) notwithstanding her age.<sup>44</sup> Accordingly, the consent of a “mature” or “Gillick” minor can be equally valid with the consent of a competent adult.

The affirmation of the possibility of a mature minor has generated controversy, not only because of its substantial merit, but also because of the existence of section 8(3) of the Family Law Reform Act 1969. The Act treats individuals between the age of 16 and 18 as able to consent, but in section 8(3) adds that “nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted”. It can plausibly be argued<sup>45</sup> that the meaning of this section is that the parental right to consent on behalf of a child remains intact, even in the ages 16-18. *A fortiori* then, this provision must also apply to “mature minors”. This being the case a problematic scenario may emerge: what if the mature child and her parents do not take the same stance towards a proposed provision, that is to say what if the child consents and the parents refuse or vice versa? Controversy has arisen mainly referring to the latter possibility, in the event of a mature minor that refuses to be treated. Should such a refusal be respected?

Although the decision in Gillick insists that parental rights cease as soon as the minor reaches capacity, the validity of a refusal to consent remains an open question, especially when this involves the possibility of a serious injury or death. In a series of cases, the courts attempted to provide an answer to this issue, essentially assuming that in the case of minors, consent and refusal are not and should not be considered as logically equivalent alternatives.<sup>46</sup> A combined reading of *Re R*<sup>47</sup> and *Re W*<sup>48</sup> provides probably the most accurate understanding of the position. In these cases, the courts insisted that the wishes of the minor must always be taken very seriously. Yet, when a refusal may lead to a severe deterioration of the minor’s health, this refusal need not be regarded as determinative. This being the case, the consent of the parents may provide the justification necessary for performing a medical operation.

In this section, my aim was to show that consent functions as a defence against the tort of battery. For this reason, I explained the conditions in terms of which consent

<sup>44</sup> It is important to notice that the assessment of the capacity of a child is not exactly the same as that referring to the capacity of an adult. For further analysis, see J. Montgomery, 2003, p. 385.

<sup>45</sup> See in details, J.K. Mason and G.T. Laurie, 2005, pp. 369-370.

<sup>46</sup> For this point, see J.K. Mason and G.T. Laurie, 2005, pp. 371-372. For a more critical perspective see L. Edwards, “The Right to Consent and the Right to Refuse: More Problems with Minors and Medical Consent” [1993] *Juridical Review* 52.

<sup>47</sup> (1992) 7 BMLR 147.

<sup>48</sup> *Re W (a minor) (medical treatment)* [1992] 4 All ER 627, (1992) 9 BMLR 22.



to treatment is lawful and thus can perform its function. Yet, it must be clear by now that doctors often treat patients that cannot validly consent. This does not mean that these treatments are unlawful, only that they are justified on different bases. In the next section, I am discussing the most significant of these justifications.

## **b) The best interests principle.**

It is a basic tenet of both civil and criminal law that an otherwise unlawful act becomes lawful, if one acts out of *necessity*. This idea constitutes the basis of an additional defence against ostensibly tortuous behaviour, one that is very significant in the context of medical law. Here, the general doctrine of necessity takes the form of the so-called “best interests” principle, according to which a medical procedure is not unlawful when it is performed in order to serve the best interests of the patient. Given that consent to treatment is the only applicable defence when a patient has the capacity to decide for herself, the best interests principle does not apply to competent patients. However, as the previous section has already shown, in many situations doctors have to treat patients not competent to make decisions. When this is the case, the best interests principle is the normative device most often used to justify the lawfulness of medical procedures.<sup>49</sup>

In any attempt to understand how the best interests principle works in practice a number of issues must be clarified. Although these can be expressed in different ways, the main questions can be summarised as follows: what exactly is meant by the ambiguous term “best interests”, who is to make its assessment and, crucially, on what criteria? In order to discuss these issues, it is necessary to keep in mind that the best interests principle is being developed within the context of adjudication as a dynamic concept and that, for this reason, it cannot easily be defined. In addition, the general applicability of the principle renders this problem more difficult to tackle. Since the principle applies to a very wide set of different medical scenarios, its exact conceptualisation is very much dependent on the exigencies of particular cases. Accordingly, it is more useful to begin with a general exposition of what the best interests principle possibly means and then to explore a particular medical context as a case study, where the principle is actually applied.

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<sup>49</sup> It is important to stress here that exactly because the best interests principle is, in law, a defence against the possibility of liability, it works essentially in a one-way manner. A doctor can justify her actions in terms of the best interests principle; yet, she cannot be forced to offer care *against her clinical judgment*, even if it is generally understood that this care would actually be in the best interests of the patient. For the judicial acknowledgement of this thesis, see *R v. Ealing DA, ex p. Fox* [1993] 3 All ER 170 and *Re J* [1992] 4 All ER 614.

Generally speaking, one may distinguish between two possible versions of the principle. The first is rather obvious: the term "best interests" can be understood as referring to the medical interests of the patient, in which case a doctor acts lawfully, when her acts serve the interests of her patient as these are defined by her medical condition. From this point of view, any action that influences positively the health of the patient is in her best interests; this formulation of the principle obviously covers everything that has a therapeutic effect, no matter what this may be. Nevertheless, a different version of the principle can also be sustained. The best interests test may refer to the patient's general interests, namely to her general welfare given her life situation, and not only to a particular medical condition. This is obviously a much wider formulation of the principle that justifies any medical intervention that may have a positive impact on the general welfare of the patient.

This fundamental conceptual distinction becomes particularly relevant, when one considers the powers that the courts have in reference to the best interests of the incompetent. These powers are linked in a very significant extent with the concrete judicial procedure in terms of which the question of best interests has occurred. In turn, this procedural aspect depends on distinguishing between adults and minor patients. In the latter case, courts usually intervene within the auspices of the wardship jurisdiction:<sup>50</sup> when a child has been made a ward of court, she is in the care of the court and no decision can be made or action be taken without the court's permission.<sup>51</sup> In giving this permission, the court in charge is to ensure that the welfare of the child is enhanced in the best possible way and, thus, has the authority to sanction or prohibit anything that is proposed (even the doctors' or the parental views)<sup>52</sup> based on a wide range of criteria that may exceed the strictly medical assessment of the situation. On the contrary, in the case of adult patients the courts do not directly have such powers. After the abolition of the *parens patriae* jurisdiction,<sup>53</sup> the courts can only be involved indirectly when they are

<sup>50</sup> The wardship jurisdiction is not the only route that may be followed in order to place a minor under judicial protection. Other alternatives include the "inherent jurisdiction" and the issuing of special orders under section 8 of the Children Act 1989.

<sup>51</sup> See in details N.V. Lowe and R.A.H. White, *Wards of Court* (2<sup>nd</sup> edition, London: Butterworths, 1986).

<sup>52</sup> It must be stressed here that when the doctors and the parents seriously disagree on the proper management of a minor's health, judicial intervention must be sought for the conflict to be resolved. This is based on the reasoning in *Glass v. United Kingdom* [2004] 1 FLR 1019, (2004) 77 BMLR 120, where it was held that a health authority that does not ask for judicial intervention to override a parental refusal to consent, is in breach of a child's human right to privacy; also, on the guidelines included in *Practice Direction (CAFCASS: Representation of Children in Family Proceedings)* [2004] 1 FLR 1190 and in *Practice Direction (Family Proceedings: Representation of Children)* [2004] 1 WLR 1180.

<sup>53</sup> For an analysis of this issue, see G.T. Laurie, "Parens Patriae in the Medico-legal Context: the Vagaries of Judicial Activism" (1999) 3 *Edinburgh LR* 95.

asked to issue a declaration of lawfulness in advance of a proposed medical interaction.<sup>54</sup> In this scenario, they are called to opine on a medical course of action that the doctors believe is in the best interests of their patient. It follows that the relevant assessment is much more explicitly oriented to the medical interests of the patient and that a narrower version of the best interests test is more apposite.

Having framed the background of the best interests principle in such terms, I will now explore a particular medical context within which the principle has been intensely applied. For this purpose, I have chosen the *sterilisation of females* on the basis that here many of the controversies that surround the principle are more easily identifiable.<sup>55</sup> This is because quite often the sterilisation of an incompetent patient (usually one with a certain degree of mental health problems) is not always associated with a direct therapeutic benefit, but rather with her general ability to cope better with life. Accordingly, the distinction between medical and general best interests (which seems to run in parallel with a distinction between therapeutic and non-therapeutic interventions) appears in a very clear light here. In discussing the relevant case law, it is once again useful to mobilise the distinction between minor and adult patients. It is also helpful to keep in mind that in all these cases, either the doctors in charge of the patient's care or members of her family claim that sterilisation is appropriate for at least one of the following reasons: a) because the medical condition of the patient is such that a necessary medical intervention will have the side-effect of sterilising the patient; b) because it is difficult for the patient (or her carers) to cope with the management of her menstrual cycle and c) because of the possibility of the patient becoming pregnant, when she (or her carers) would be unable to deal with the pregnancy as such or with the upbringing of a child.

In the case of minors the first apposite case was *Re D (a minor)*.<sup>56</sup> Here, Heilbron J held that she could not authorise the sterilisation of a young girl for non-therapeutic reasons, after having carefully scrutinised the medical evidence in favour of the operation. This remained the dominant position until the decision in *Re B*,<sup>57</sup> in the late 80s. In this case, B was a severely handicapped 17-years-old with a mental age of five to six years; the case proceeded on the assumption that it was likely that she would become

<sup>54</sup> Things are somewhat different now, after the passing of the Adults with Incapacity (Scotland) Act 2000 and the Mental Capacity Act 2005. Since I am here discussing the common law position only, I will refer my comments on the content of these Acts to subsequent sections of this chapter.

<sup>55</sup> Once again, let me stress that the best interests principle is so widely applied that any other medical context could also be used as an example.

<sup>56</sup> [1976] Fam 185, [1976] 1 All ER 326.

<sup>57</sup> *Re B (a minor) (wardship: sterilisation)* [1988] AC 199, [1987] 2 All ER 206, HL.

pregnant and that she would not be able to cope with it. In order to avoid that, two options were available according to the medical view: she would either have to take contraceptives for the totality of her fertile years or she could be sterilised. On the basis of the welfare of B, the House of Lords authorised the proposed sterilisation. This is an important decision because a number of interesting points were explicitly raised. Crucially, Lord Oliver argued that “the distinction between “therapeutic” and “non-therapeutic” purposes of this operation... is irrelevant”<sup>58</sup> and that it does not make any sense to distinguish between preventive medicine and therapy as far as the interests of the child are concerned. It follows that the assessment of the best interests of the patient goes beyond what a purely therapeutic analysis of her condition may indicate and has to be oriented to her general welfare.<sup>59</sup> Yet, it seems that both in *Re B* and in the subsequent *Re M*<sup>60</sup> and *Re P*<sup>61</sup>, the medical assessment of the children significantly contraindicated the possibility of pregnancy, for purely medical reasons. Therefore, it seems to be the case that the delineation of the general welfare of a child is closely linked with the medical evaluation of her condition.

As far as adult patients are concerned, the most significant case is probably *Re F*.<sup>62</sup> The importance of this case is twofold, namely *both* in terms of the criteria that it applies in dealing with the substantial question *and* in terms of the procedural analysis regarding when it is necessary for a court to intervene in order to authorise a proposed sterilisation. Regarding the latter issue, the House of Lords confirmed that in the case of adults, an application for a declaration of lawfulness would be the only way to achieve judicial intervention. Indeed, it would be a matter of good medical practice to ask for such an authorisation.<sup>63</sup> Currently, this “good practice” has become compulsory: the existing Practice Direction declares that a decision to sterilise an incompetent person requires the prior sanction of the High Court.<sup>64</sup> Regarding the substance of the decision,

<sup>58</sup> See [1987] 2 All ER 206, at 213.

<sup>59</sup> For arguments in favor and against the merits of this decision, that arguably faced severe academic criticism, see J.K. Mason and G.T. Laurie, 2005, pp. 133-134, with many references to a number of commentators.

<sup>60</sup> *Re M (a minor) (wardship: sterilisation)* [1988] 2 FLR 497, [1988] Fam Law 434.

<sup>61</sup> *Re P (a minor) (wardship: sterilisation)* [1989] 1 FLR 182, [1989] Fam Law 102. In both these cases the outcome was similar.

<sup>62</sup> *Re F (mental patient: sterilisation)* [1990] 2 AC 1, sub nom *F v. West Berkshire Health Authority* [1989] 2 All ER 545.

<sup>63</sup> Unless a sterilisation operation is to be performed for a genuine therapeutic reason. In this case, no prior authorisation of the court is necessary as it was held in *Re E (a minor) (medical treatment)* [1991] 2 FLR 585, (1992) 7 BMLR 117 (this case refers to a minor patient but it seems that its premises apply to adult patients as well – see, amongst others *F v. F* (1992) 7 BMLR 135, where the conditions on the basis of which there is no need to ask for judicial intervention are clearly laid down). Also, in *Re H* [1993] 1 FLR 28, it was held that prior authorisation is not in general necessary as far as diagnostic procedures are concerned.

<sup>64</sup> See in details *Practice Notice (Official Solicitor: Declaratory Proceedings: Medical and Welfare Decisions for Adults who Lack Capacity)* [2001] 2 FCR 158, (2002) 65 BMLR 72.

its outcome is rather surprising. Once again, it is emphasised that the lawfulness of a sterilisation is to be assessed in terms of the best interests of the patient. However, the content of the principle is to be evaluated according to the “Bolam test”: this originates from the law of medical negligence and it provides that a doctor is acting lawfully, when his actions are in accordance with a responsible body of medical opinion.<sup>65</sup> In the present context, this implies that the requirement that an operation is in the best interests of the patient is met when the doctor in charge believes that this is the case and his assessment finds support from a responsible body of medical opinion. This method for defining the content of the best interests principle, effectively medicalises the issue, since it allows its medical assessment to be totally determinative and minimises to a significant extent the scope of judicial scrutiny. Quite unsurprisingly, the import of a norm emanating from the law of negligence into a substantially different matter has been seriously criticised.<sup>66</sup> Yet, in a series of subsequent cases the judicial dicta of lower courts remained in line with the decision in *Re F*; for instance, the sterilisation of the patient in *Re W*<sup>67</sup> was also authorised on the basis of the Bolam test. However, this uneasiness regarding the combination of the best interests principle with the Bolam test has been somehow dampened down given the reasoning in *Re S*.<sup>68</sup> There, the Court of Appeal held that the Bolam test only delineates a range of alternative possibilities that a responsible doctor could follow. However, the best interests principle demands that only one of them, serves “best” the interests of the patient. This implies that a double assessment is necessary, only the first stage of which is defined in terms of the Bolam test. Its second stage, namely the decision on what constitutes the “best” option depends on a variety of factors, not necessarily controlled by medical expertise.

So, what conclusions can be reached regarding the conceptualisation of the best interests principle? It seems to me that two tendencies can be simultaneously observed. First, the courts are willing to perceive the best interests quite widely, as including more than the strictly medical best interests of the patient. Indeed, it can be argued that when it is obvious that from a therapeutical perspective a medical intervention is beneficial, it is not even necessary to ask for previous judicial authorisation. Secondly, it seems that the strongest factor in determining the exact content of the principle is the assessment of the situation on behalf of the doctor. Especially the involvement of the Bolam test is a very

<sup>65</sup> I will discuss extensively the Bolam test in the next session of this chapter.

<sup>66</sup> See amongst others D. Ogbourne and R. Ward, “Sterilization, the Mentally Incompetent and the Courts” (1989) 18 *AngloAmerican LR* 230.

<sup>67</sup> *Re W (Mental patient: sterilisation)* [1993] 1 FLR 381, [1993] Fam Law 222.

<sup>68</sup> *In re S (adult patient: sterilisation)* [2000] 1 FLR 465, [2000] Fam Law 322, revisited [2001] 3 Fam 15, [2000] 3 WLR 1288.



strong indication of the lingering importance of the doctors' perception on what the interests of the patient entail.<sup>69</sup> Although the impact of professional expertise is moderated according to the reasoning in *Re S*, as well as in a series of recent cases outside the context of sterilisation,<sup>70</sup> we have not yet reached a stage where the principle is significantly dissociated from professional assessments. This being the case, the best interests principle counters the way that consent to treatment functions: whereas the latter expresses the autonomy of the patient against the medical establishment, the former restates the power of the benevolent, expert doctor in defining what should be done.

### c) Medical negligence.

Medical negligence is a particular instance of the general law of negligence. Accordingly, for an action in negligence to be successful, the patient must show that the conditions that any such action must meet are satisfied. These include that a duty of care exists, that the doctor acted in breach of the standard of care integral to the duty, and that the patient suffered some damage caused by the breach of the duty.<sup>71</sup> Although all of these conditions are determinative for the final assessment of a claim, in what follows I will only deal with the standard of care and with the notion of damage. This is because the affirmation of the existence of a duty of care is relatively straightforward within a usual medical interaction,<sup>72</sup> and because the problem of causation is no different in this context than in any other type of negligence (although a significant number of medical negligence claims fail because of lack of causation).

The clear identification of the exact standard of care, against which an alleged breach can be evaluated, tends to be a rather latent issue in general negligence. The very occurrence of an undesirable outcome in the interactions of everyday life is often enough to indicate that a duty of care has been breached. The main question is only whether the duty exists or not. If it does, then an undesirable outcome strongly suggests that the defendant has been in breach of the standard related to this duty; what exactly is this standard remains obscure. In the medical context, the problem is that this "conflation"

<sup>69</sup> For the general reluctance of the courts to counter the medical assessment of best interests, see J. Montgomery, 2003, pp. 400ff.

<sup>70</sup> For an analysis of these cases see J.K. Mason and G.T. Laurie, 2005, pp. 363-365 with further references.

<sup>71</sup> I assume, here, that usually an action in negligence is raised by a patient against her doctor (or against the health authority that employs the doctor). In terms of the latter scenario, let me just say that the vicarious liability of hospitals is well established.

<sup>72</sup> See the reasoning in *Barnett v. Chelsea and Kensington Hospital Management Committee* [1969] 1 QB 428, [1968] 1 All ER 1068, [1968] 2 WLR 422.



between an undesirable outcome and the affirmation that the duty of care has been broken is not to be trusted. This is because medical practice is inherently risky and hazardous and therefore, an unfortunate occurrence is not necessarily attributable to human error. It can equally be a matter of natural eventuality.<sup>73</sup> Since the final outcome cannot serve as such, as an indicator of a sub-standard performance, the need to define clearly what is the standard of care required by the doctor (in other words what exactly she is supposed to be doing) comes into the forefront in medical negligence claims.

The main rule regarding the proper standard of care has been laid down by McNair J in *Bolam v. Friern Hospital Management Committee* as follows:<sup>74</sup>

“The test is the standard of the ordinary skilled man exercising and professing to have that special skill”.

Effectively, this formulation dictates that the standard of care is defined by the degree of competence that is reasonably expected by any ordinarily skilful doctor that performs under the same circumstances as the defendant.<sup>75</sup> Although this is a rather clear formulation of a legal rule,<sup>76</sup> and indeed one, which is compatible with the general trend regarding the identification of the standard of care expected by members of professions,<sup>77</sup> it generates a significant practical problem for plaintiffs. It appears that in real terms it is quite difficult to prove that the performance of the defendant falls short of the standard.<sup>78</sup> This problem is intensified, as further decisions made clear that this is essentially a minimal standard and that the doctor needs only to prove that at least a small number of respected professionals would accept what she did as proper.<sup>79</sup> Furthermore, in *Maynard v. West Midlands RHA*,<sup>80</sup> the House of Lords held that in the case of disagreement between different schools of thought about the proper medical conduct, the courts are not to choose one of them as the determinant of the standard of

<sup>73</sup> For an analysis of the crucial distinction between professional errors, mistakes and natural eventualities, see A. Merry and A. McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001).

<sup>74</sup> [1957] 2 All ER 118, at 121, [1957] 1 WLR 582, at 586.

<sup>75</sup> For the similar position in Scotland, see *Hunter v. Hanley* 1955 SC 200.

<sup>76</sup> This formulation, usually depicted under the term “the *Bolam* test”, became undoubtedly the crucial test for medical negligence when it was adopted by the House of Lords in *Whitehouse v. Jordan* [1981] 1 All ER 267.

<sup>77</sup> The implication here is that when it comes to “professional negligence”, the significance of the actual professional practice is very intense. Whereas for non-professionals, the ordinary conduct relevant to the issue at stake is just persuasive evidence for the standard of care, in the case of professionals this tends to be accepted as a binding rule in itself. For further analysis and an attempt to explain the difference, see J. Healy, *Medical Negligence: Common Law Perspectives* (London: Sweet & Maxwell, 1999), pp. 63-64.

<sup>78</sup> According to the National Audit Office (in *Handling Clinical Negligence Claims in England*), 76% of the relevant actions fail for a variety of reasons.

<sup>79</sup> For instance, in *Hughes v. Waltham Forest HA* [1991] 2 Med LR 155 it was held that the very support from eminent expert witnesses defies any allegation of negligence. In *Defreitas v. O'Brien* [1995] 6 Med LR 108 CA, the court rejected the view that the body of medical opinion in favor of the defendant must be substantial (of course it is of crucial significance that this case deals with very specialised doctors, the number of which is by definition very small).

<sup>80</sup> [1985] 1 All ER 635.

care: it is enough for the defendant to show that at least one body of medical opinion sustains her action, notwithstanding the fact that this may be seriously opposed by other doctors.

Perhaps not surprisingly, this normative edifice has attracted severe criticism as being particularly lenient towards the medical profession.<sup>81</sup> Indeed, the underlying tendency appears to be an over-reliance on the assessment of other medical professionals: a doctor's actions fall below the proper standard of care, *only* if her peers think that this is the case. On the contrary, if the profession (even a small group from within the profession) validates the performance of the defendant, the courts explicitly reject the possibility that they may intervene and substantially scrutinise the alleged breach of the standard.

Against such a background, the House of Lords was called to opine in *Bolitho v. City & Hackney HA*.<sup>82</sup> This was a rather complicated case, especially because it concerned a hypothetical situation, regarding an incidence of non-attendance. A doctor did not attend his patient, who ultimately suffered brain damage. That non-attendance was in breach of a duty of care was not in dispute; however, and given that only intubation could have saved the patient, the health authority argued that the doctor was not liable for the damage, on the premise that even if the doctor was present, she would still not have intubated the patient and this would have been in accordance with a responsible body of medical opinion. In essence, this is a defence on the basis of lack of causation, but the whole argument is based on the hypothesis that the (hypothetical) non-intubation would not be negligent in terms of the Bolam test. In responding to this defence, the House of Lords accepted the logical premises of the argument, but proposed a revision of the Bolam test, according to which only a "responsible" medical opinion should be relevant and therefore in a case where the medical opinion, proposed as providing the basis for the standard of care, cannot withstand logical analysis, a judge is entitled to discard it.<sup>83</sup> Interestingly, even this revised formulation of the Bolam test validated the position of the health authority: on the facts of the case, it was held that a medical opinion supporting non-intubation was indeed reasonable. Yet, and leaving aside the

<sup>81</sup> See amongst others, K. Norrie, "Common Practice and the Standard of Care in Medical Negligence" (1985) *Juridical Review* 145.

<sup>82</sup> [1997] 4 All ER 771.

<sup>83</sup> Yet, Lord Browne-Wilkinson explicitly accepted that "it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable" (*ibid.* at p. 779).

outcome of the case, there remains no doubt that this was a significant step in the development of the test of the standard of care.<sup>84</sup>

Arguably, an important shift can be detected here,<sup>85</sup> even with the minimal content of allowing the judiciary to disregard these medical dicta that cannot withstand logical analysis. In the light of this shift, subsequent decisions were eagerly anticipated as crucial for the clarification of the test for the standard of care after *Bolitho*.<sup>86</sup> Yet, the case law after *Bolitho* allows for different interpretations. It is clear that at least in some cases, such as *Sharp v. Southend HA*<sup>87</sup> and *Marriot v. West Midlands RHA*<sup>88</sup> the reasoning in *Bolitho* was followed and medical evidence was subjected to judicial analysis.<sup>89</sup> On the contrary, the decisions in cases such as *Briody v. St Helen's & Knowsley AHA*,<sup>90</sup> *Hallatt v. NW Anglia HA*<sup>91</sup> and *Rhodes v. West Surrey and NE Hampshire HA*<sup>92</sup> seem to be in favour of the traditional Bolam approach. Also, it is not necessarily the case that adhering to the test accepted in *Bolitho* would make things easier for plaintiffs. For instance, in *Wisniewski v. Central Manchester HA*,<sup>93</sup> the Court of Appeal accepted the premises of *Bolitho* but added that "... it is quite impossible to hold that the views sincerely held by doctors of such eminence cannot logically be supported at all".<sup>94</sup> Indeed, it seems that the possibility of an illogical medical opinion is very extreme.

So, what can be said as a conclusion regarding the standard of care? Although it seems fair to claim that the courts are now in a position to scrutinise professional expertise, the extent of this option is so limited that still we are dealing with a professionally defined standard of care. This is not to say that the decision in *Bolitho* is insignificant: on the contrary, it constitutes an explicit indication of the judicial reluctance

<sup>84</sup> For a very explicit argument in favor of the decision as a step towards the right direction, see A. Grubb, "Commentary" (1998) 6 *Medical Law Review* 378.

<sup>85</sup> One should not believe that the decision in *Bolitho* appeared as a total surprise: in previous cases, more notably in *Smith v. Tunbridge Wells HA* [1994] 5 Med LR 334 (a case that refers to information disclosure), traces of a similar approach can also be found. For further examples, see J. Montgomery, 2003, pp. 172-173.

<sup>86</sup> Especially since not everyone was persuaded that the traditional Bolam test was now dead. See, amongst others M. Brazier and J. Miola, "Bye-Bye Bolam: A Medical Litigation Revolution?" (2000) 8 *Medical Law Review* 85.

<sup>87</sup> [1997] Med LR 299.

<sup>88</sup> [1999] Lloyd's Rep. Med. 23.

<sup>89</sup> It must be stressed though that in *Marriott*, the crucial factor seems to be the concept of "reasonableness" instead of the concept of logic and thus it is possible to interpret this case as offering another alternative for the formulation of the Bolam test.

<sup>90</sup> [1999] Lloyd's Rep. Med. 185, CA.

<sup>91</sup> [1998] Lloyd's Rep. Med. 197.

<sup>92</sup> [1998] Lloyd's Rep. Med. 256.

<sup>93</sup> [1998] Lloyd's Rep. Med. 223, CA.

<sup>94</sup> [1998] Lloyd's Rep. Med. 223, CA, at p. 237 by Brooke LJ.

to extend the significance of an unchallenged Bolam test.<sup>95</sup> Yet, as far as the standard of care is concerned, the impact of *Bolitho* is rather marginal.<sup>96</sup>

Let me now turn to the separate issue that I want to discuss in this section, namely the notion of damages. Just to provide a reminder, in a negligence action the plaintiff asks to be compensated on the allegation that she suffered damages as a result of the defendant's conduct, in other words because she was harmed. *Conceptually* speaking, harm is almost always unproblematic: undesirable outcomes are usually understood as harmful. Yet, in a particular set of cases the very notion of harm (and accordingly, the possibility of being compensated for damages) is itself contested, in the sense that what the plaintiff perceives as a harmful outcome is not (or should not) be conceptualised as such. Here, I have in mind two "types" of medical scenarios, where the possibility of the contestability of the very notion of harm occurs:<sup>97</sup> these are known under the technical terms "wrongful pregnancy"<sup>98</sup> and "wrongful birth".<sup>99</sup>

Actions for wrongful pregnancy commonly occur in connection with a failed sterilisation operation. Usually, one of the partners in a marital relationship<sup>100</sup> is voluntarily sterilised, this being a radical means of contraception. Such an operation may go wrong for two reasons: either because it was performed negligently or because there exists an inherent risk that the result of a successful operation is reversible and the risk actually materialised. In the second scenario, it is possible that the doctor in charge has been negligent in not informing the couple involved for the possibility of reversibility. In any case, a couple that has *bona fide* believed that its procreative capability has ceased (in effect this was exactly the desired outcome of the initial decision to be sterilised), may end up with an uncovenanted child.<sup>101</sup> Assuming, that the doctor in charge of the operation has been in breach of her duty of care, a claim in negligence arises, which usually includes two heads of damages: first, damages that derive from the pregnancy

<sup>95</sup> For this point, see J.K. Mason and G.T. Laurie, 2005, p. 317.

<sup>96</sup> For further analysis, see J. Montgomery, 2003, pp. 175-177.

<sup>97</sup> Arguably, a third type of scenario, the so-called "wrongful life" cases raises the same problems. Yet, because of its limited practical significance, I will not discuss it here. For a comprehensive analysis, although from a philosophical perspective, see E. Haavi-Moreim, "The Concept of Harm Reconceived: a Different Look at Wrongful Life", (1988) 7 *Law and Philosophy* 3.

<sup>98</sup> Sometimes, the term "wrongful conception" is used to denote the same thing. For an analysis of why the term used in the main text is preferable, see J.K. Mason and G.T. Laurie, 2005, p. 168.

<sup>99</sup> The complexity of these scenarios is such that they have triggered a rather broad and fruitful academic interest. The relevant literature is quite extensive, but I think that a solid presentation of the main issues can be found in N. Priaulx, "Joy to the World! A (Healthy) Child is Born! Reconceptualising "Harm" in Wrongful Conception" (2004) 13(1) *Social & Legal Studies* 5; L. Hoyano, "Misconceptions about Wrongful Conception" (2002) 65(6) *Modern Law Review* 883; J.K. Mason, "Wrongful Pregnancy, Wrongful Birth and Wrongful Terminology" (2002) 6 *Edinburgh LR* 46 and "Unwanted Pregnancy: A Case of Retroversion?" (2000) 4 *Edinburgh LR* 191.

<sup>100</sup> More often than not, this would be the male partner.

<sup>101</sup> I borrow the term from J.K. Mason and G.T. Laurie, 2005, p. 168.



itself and may include loss of earnings, personal discomfort etc; secondly, and more importantly for my present purposes, damages that refer to the cost of bringing up the child that has been conceived. I will not deal at all with the first head of damages, since the normal rules of negligence apply there. On the contrary, the second head is conceptually problematic, given that in essence compensation is asked for the birth of a child. The question that occurs is straightforward: is the birth of a child a proper basis for a claim of damages?

The courts in the UK have struggled quite a lot with this issue. A number of cases have so far been decided with interesting, although rather complicated, results. In order to understand the relevant dicta, one has to keep in mind that the courts usually employ a distinction regarding the health of the child conceived as a result of wrongful pregnancy; accordingly, there is an important difference between giving birth to a healthy and to an unhealthy child.

In the first of the apposite cases,<sup>102</sup> the claim was rejected, as Jupp J argued that “it is an assumption of our culture that the coming of child into the world is an occasion for rejoicing”.<sup>103</sup> Nonetheless, soon afterwards the Court of Appeal nullified this view: in *Emeh*<sup>104</sup> it was held that there is no reason why the cost of raising a child should not be perceived as a proper head of damage. This reasoning appeared as the final word on the issue and a set of subsequent decisions<sup>105</sup> followed it completely. However, this image of settled precedent was to be radically changed due to the decision of the House of Lords in *McFarlane v. Tayside Health Board*.<sup>106</sup> Following different and occasionally rather unclear reasoning (which seemed to include arguments regarding reasonableness, distributive justice, incommensurability and the idea of birth as a blessing),<sup>107</sup> the Law Lords unanimously held that the cost of raising a *healthy* child should not be recovered. In this respect they significantly overruled the position that was held until then.<sup>108</sup> Yet, since their decision referred to healthy children, the position was unclear in reference to unhealthy children. This was clarified in *Parkinson v. St James and Seacroft University Hospital NHS Trust*,<sup>109</sup> where it was held that it is fair, just and reasonable to compensate for the

<sup>102</sup> *Udale v. Bloomsbury Area Health Authority* [1983] 2 All ER 522, [1983] 1 WLR 1098.

<sup>103</sup> *Ibid.* at p. 531.

<sup>104</sup> [1985] QB 1012, [1984] 3 All ER 1044, CA.

<sup>105</sup> See amongst others *Robinson v. Salford Health Authority* (1992) 3 Med LR 270 and *Allen v. Bloomsbury Health Authority* [1993] 1 All ER 651, (1993) 13 BMLR 47.

<sup>106</sup> [2000] AC 59, 2000 SC 1, HL.

<sup>107</sup> I will revisit the reasoning of this case in the penultimate part of this chapter, so there is no reason to be very extensive here.

<sup>108</sup> The decision faced significant academic criticism. See, amongst others, J. Thomson, “Abandoning the Law of Delict?” 2000 *SLT* 43.

<sup>109</sup> [2002] QB 266, [2001] 3 All ER 97.

additional expenses of bringing up an unhealthy child (additional in comparison with the expenses of raising a healthy child that are not recoverable). This reasoning was further clarified by the House of Lord decision in *Rees v. Darlington Memorial Hospital NHS Trust*.<sup>110</sup> There, it was clearly held that the only disability that matters is the disability of the child born. Accordingly, the possibility of a disabled mother is irrelevant:<sup>111</sup> when a disabled mother is to raise a healthy child, the reasoning in *McFarlane* persists and no compensation is awarded. Therefore, as a coda, only the additional costs of bringing up an unhealthy child are compensated in wrongful pregnancy, at least as things stand for the time being.

An action for wrongful birth is similar, but conceptually distinct. Here, the negligence occurs during pregnancy and more particularly during pre-natal screening. Effectively, the claim is based on the allegation that the doctor failed to realise and subsequently to inform the prospective parents about a foetal abnormality, either because of negligently performed or of total lack of pre-natal screening. As a result, the parents did not have the opportunity to consider a termination of pregnancy and ended up with a heavily disabled child. Once again, a similar question arises: should they be compensated for the cost of raising this child?

Leaving aside the fact that the relevant cases may fail because of problems with causation (the parents have to prove that if they knew about the defect, they would have decided to terminate the pregnancy),<sup>112</sup> generally speaking the courts are willing to answer the question positively. In a series of cases that include *Anderson v. Forth Valley Health Board*,<sup>113</sup> *Nunnerley v. Warrington Health Authority*<sup>114</sup> and *McLelland v. Greater Glasgow Health Board*,<sup>115</sup> the courts awarded compensation in total.<sup>116</sup> However, the decision of the House of Lords in *McFarlane* also affected wrongful birth cases: the ultimate award is now modified to exclude the cost of raising a healthy child, in accordance with the parallel position in wrongful pregnancy. This modification is included in a series of cases

<sup>110</sup> [2004] AC 309, [2003] 4 All ER.

<sup>111</sup> This was a relevant issue in this case, because Mrs Rees was severely handicapped and the previous decision of the Court of Appeal had accepted her claim, although it involved the birth of a healthy child. For the reasoning of the Court of Appeal see [2002] 2 All ER 177, (2002) 65 BMLR 117 and the very similar arguments in *Groom v. Selby* (2002) 64 BMLR 47, [2002] Lloyd's Rep Med 1, CA.

<sup>112</sup> This is why the claim in *Gregory v. Pembrookshire Health Authority* [1989] 1 Med LR 81 failed.

<sup>113</sup> (1998) 44 BMLR 108, 1998 SLT 588.

<sup>114</sup> [2000] Lloyd's Rep Med 170.

<sup>115</sup> 1999 SC 305, 1999 SLT 543.

<sup>116</sup> To be precise, in these cases damages include the shock and distress the parents suffered from the birth of a disabled child and the cost of upbringing the child.



decided after *McFarlane*, most notably *Rand v. East Dorset Health Authority*<sup>117</sup> and *Hardmann v. Ammin*.<sup>118</sup>

With this comment, I have concluded what is effectively the first part of my exploration of medical negligence. A significant issue remains to be discussed. This is exactly the subject matter of the following section.

#### **d) Information disclosure and its relationship to negligence.**

The discussion has so far dealt with negligence in the course of diagnosis and treatment. Nonetheless, this is not the only context within which medical negligence may occur. The interaction between a doctor and a patient involves also a stage of communication between the two parties; this is necessary, not only in terms of sound medical practice but also because of the legal requirement of consent. Consent cannot be given in a communicative vacuum. At least some information must be disclosed from the doctor to the patient, so that the latter can consent or refuse in an informed manner. Without information the very concept of consent would be essentially redundant - hence the term "informed consent",<sup>119</sup> which implies that the patient has acquired some knowledge of the nature and the possible risks of the proposed medical intervention.

It is possible that a negligence action may originate in this context. Since the stake here is information disclosure, the complaint of the pursuer refers to what has actually been disclosed. To be more precise, what matters is whether an inherent hazard of the (properly performed on the basis of proper diagnosis) intervention has been revealed or not before consent was given. If this had not been the case and during the medical intervention the risk actually materialised, the patient may have a claim in negligence. For reasons of clarity, let me say that this claim usually takes the following form: "I was not told in advance that there was an inherent risk involved in the proposed operation; this risk materialised and as a result I suffered damages; if I had known about the risk that was not disclosed to me, I would not have consented to what was proposed and the operation would not have been performed; therefore I ask compensation for the damages I suffered".

<sup>117</sup> [2000] Lloyd's Rep Med 181, (2000) 56 BMLR 39.

<sup>118</sup> [2000] Lloyd's Rep Med 498, (2000) 59 BMLR 39.

<sup>119</sup> The use of the rather odd term "informed consent" is not without its critics, especially from the point of view of medical ethics. See, amongst others, O. O' Neil, "Some Limits of Informed Consent" (2003) 29 *Journal of Medical Ethics* 4 and O. Corrigan, "Empty Ethics: The Problem with Informed Consent" (2003) 25 *Sociology of Health and Illness* 768.

This is clearly a negligence claim:<sup>120</sup> the doctor is blamed for misconduct during the process of information disclosure and therefore the general law of medical negligence applies. However, two particular issues potentially distinguish cases of informed consent from those that relate to diagnosis and treatment. The first issue refers to the exact delineation of the standard of care; the second to the problem of causation. As to the former, the troubling question is whether the test that substantiates the standard of care in diagnosis and treatment is also relevant here, since information disclosure is not necessarily a matter of professional expertise alone. As to the latter, the problem is that the plaintiff has to prove that if she had known about the undisclosed risk, she would not have consented to the operation: the need to sustain this assertion is fraught with difficulty. I will explore these issues in turn.

As to the standard of care, the first cases that dealt with the problem assumed that negligence in the context of informed consent is no different than negligence in diagnosis and treatment. Both in *Chatterton v. Gerson*<sup>121</sup> and in *Hills v. Potter*<sup>122</sup> the court had no difficulty in applying the usual test regarding the standard of care, namely the Bolam test. In this view, what a doctor has to disclose is determined by what a responsible body of medical opinion would deem reasonable to disclose in a similar situation. This test (usually depicted under the term “professional standard”) treats disclosure as a matter that essentially falls within the domain of professional expertise, being part of the general clinical management of the patient. Yet, at least in theory, the opposite test is equally conceivable. This alternative test, often known as the “patient standard”, would treat disclosure as a matter referring to the quality of the communication between a doctor and patient, that helps the latter to reach an informed decision. In this view, it is inherently linked with the patient’s right of self-determination. As such, the standard of what should be disclosed escapes the domain of professional expertise and is determined solely by what the patient would need to know under the circumstances.<sup>123</sup>

<sup>120</sup> The fact that the complaint refers to the process of acquiring the consent of the patient, which was allegedly flawed, does not negate the fact that *consent was actually given* to an intervention of the general nature of that which was ultimately performed; therefore, there is no doubt that negligence and not battery is the appropriate cause of action. The more clear reasoning regarding the circumstances in which each of these actions is available can be found in the decision of the Supreme Court of Canada in *Reibl v. Hughes* (1980) 114 DLR (3<sup>rd</sup>) 1, per Laskin CJ at p. 10. The legal position is exactly the same in the UK, as it was later acknowledged in *Chatterton v. Gerson* [1981] QB 432, [1981] 1 All ER 257.

<sup>121</sup> *Ibid.*

<sup>122</sup> [1983] 3 All ER 716, [1984] 1 WLR 641.

<sup>123</sup> A strict adherence to this standard implies that the doctor can only exercise a minimum of clinical judgment in the context of information disclosure, since she must reveal all the relevant information to the patient. This is quite problematic in real terms, especially given the limitations of time in heavily institutionalized environments. In the light of practical problems, professional guidelines regarding the proper conduct of doctors in obtaining patients’ consent are of crucial significance. In this respect, see Department of Health, *Reference Guide to Consent for Examination or Treatment* (London: Department of Health, 2001).

Some concessions towards the direction of a patient standard were accepted in the seminal case of *Sidaway*,<sup>124</sup> which still constitutes the main authority in the context of informed consent.<sup>125</sup> Although the main test to be followed was again in tune with the professional standard,<sup>126</sup> as was clearly accepted by Lord Diplock, some caveats were simultaneously introduced.<sup>127</sup> First, it was accepted that whenever a patient is facing a "material" risk, this risk *must* be disclosed. What exactly should be understood as a material risk is indeed quite ambiguous; yet, Lord Bridge provides us with some assistance saying that, "a judge might... come to the conclusion that the disclosure of a particular risk... was so obviously necessary on the part of the patient that no reasonably prudent medical man would fail to make it".<sup>128</sup> More generally, it seems that a risk can be defined as material either when a reasonable person in the patient's condition would consider it to be significant or when a reasonable doctor would conclude that the particular patient would find the risk to be significant, had she known about it. Furthermore, it was accepted that special questions and requirements on behalf of the patient must always be answered, although it remains unclear on what basis answers should be given.<sup>129</sup> Yet, although these caveats that ostensibly undermine the professional standard must be observed, they are to be set aside whenever the doctor feels that a particular disclosure could be psychologically detrimental to the patient, especially if it could give rise to the possibility that the patient will refuse to consent to an absolutely (from the clinical point of view) necessary medical intervention. In such a scenario, the doctor enjoys a "therapeutic" or "professional" privilege that allows her to withhold the disclosure of information.

In subsequent cases,<sup>130</sup> the courts tried to strike a balance between the strict application of the professional standard, based on the Bolam test, and the caveats that

<sup>124</sup> *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* (HL) [1985] 1 All ER 643, [1985] AC 871, [1985] 2 WLR 480, 1 BMLR 132.

<sup>125</sup> In Scotland the seminal case is *Moyes v. Lothian Health Board* 1990 SLT 444, [1990] 1 Med LR 463, where the professional standard is strongly affirmed.

<sup>126</sup> With the exception of the essentially dissenting opinion by Lord Scarman, who argued in favor of the patient standard, at least as this can be assessed from the point of view of a prudent person in the position of the particular patient.

<sup>127</sup> Since the precise terms of the ruling are somehow confusing, there remains a controversy regarding what exactly it was decided. For a glimpse on the relevant debate, see M. Brazier, "Patient Autonomy and Consent to Treatment: The Role of the Law?" (1987) 7 *Legal Studies* 169; C. Newdick, "The Doctor's Duties of Care under *Sidaway*" (1985) 36 *NILQ* 243; H. Teff, "Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance?" (1985) 101 *LQR* 432 and more recently, M. Jones, "Informed Consent and Other Fairy Stories" (1999) 7 *Medical Law Review* 103.

<sup>128</sup> [1985] 1 All ER 643 at 663.

<sup>129</sup> Interestingly, in *Blyth v. Bloomsbury Health Authority* [1993] 4 Med LR 151, CA it was held that it is again the Bolam test that determines what a doctor should disclose in answering a patient's enquiry.

<sup>130</sup> Amongst others, see *Smith v. Tunbridge Wells Health Authority* [1994] 5 Med LR 334 and *Newell v. Goldberg* [1995] 6 Med LR 371.

were accepted in *Sidaway*. Still, in probably the most important of those, *Pearce v. United Bristol Healthcare NHS Trust*,<sup>131</sup> the Court of Appeal essentially reiterated the decision in *Sidaway*. Lord Woolf MR argued that the Bolam test is indeed the relevant principle regarding the delineation of the standard of proper care, but insisted that significant risks (understood from the point of the view of the reasonable patient) must be disclosed.

Even if it is concluded that the doctor is in breach of his duty of care, the plaintiff still has to prove that this breach *caused* the damage that was suffered. This generates a problem of causation that in this context seems to be particularly acute. Mainly because the proof of the causal link can only be based on the assessment of the hypothetical scenario that the patient knew the inherent risk, it appears extremely difficult to prove that on the balance of probabilities the patient would have refused to consent had she been aware of the risk. The usual norms of causation apply and it is exactly their application that generates difficulty. That is why a very significant number of claims have failed on the basis of lack of causation.

Yet, in the recent *Chester v. Afshar*<sup>132</sup> the House of Lords appeared to be ready to “bend” the traditional rules of causation in order to allow for the claim to be successful. While it was accepted that the standard rules of causation would block any hope for compensation, the majority of the Court held, on various grounds that included policy and justice, that in decisions regarding one’s health and well-being the stake is so significant that a departure from the standard rules is desirable. On this basis, the claim was ultimately successful. By reassessing the rules of causation,<sup>133</sup> the decision seems to obscure the legal position on what was until recently relatively settled legal principle.

Are there any conclusions that one can reach from this exploration of informed consent? Although the subject has attracted a lot of academic attention, which has highlighted many different issues, it seems to me that at least one conclusion is indisputable: informed consent is a clear example of how well-accepted legal principles oriented to the protection of professional expertise may potentially struggle when confronted with the concept of patient’s autonomy. The fact that the relevant claims appear as negligence claims within a communicative context, renders informed consent an exemplary plateau for the co-existence of conflicting concepts. For the time being, it

<sup>131</sup> (1999) 48 BMLR 118.

<sup>132</sup> [2005] 1 AC 134, [2004] 4 All ER 587, [2004] 3 WLR 927.

<sup>133</sup> Yet, it has been argued that a more accurate reading of the case reveals that the rules of causation are not essentially altered and that the outcome is justified because of the very delicate delineation of the exact scope of the relevant duty of care. For this argument, see M. Hogg, “Duties of care, causation and the implications of *Chester v Afshar*” (2005) 9 *Edinburgh LR* 156.

appears that professional expertise wins the day. It remains to be seen, if in the future this will still be the case.

### e) Medical confidentiality.

The regulation of medical confidentiality is a particular instantiation of the legal principles regarding confidentiality in general.<sup>134</sup> In the medical setting, confidentiality integrates two distinct stakes: the first one is the confidential nature of the doctor-patient relationship as such and the second is the security of the information arising from this relationship. Obviously, these two are so closely intertwined that they affirm the legal duty of a doctor not to disclose to third parties the content of the acquired information related to a patient.<sup>135</sup> This duty arises on any occasion when confidential information is exchanged between parties,<sup>136</sup> with the additional condition that the parties know or ought to have known that the relevant information should remain confidential and, thus, outside the public domain. There seems to be no doubt that these conditions are met within the ambit of the doctor-patient relationship and that all health care professionals owe a duty of confidentiality to their patients. For instance, the General Medical Council insists that its members owe such a duty and in its relevant guidelines,<sup>137</sup> it includes a list of more particular principles that further elaborate on how one should act in respect of this duty.

It is usually claimed that the essential justification of the duty is that it is in the public interest that confidences be respected.<sup>138</sup> Accordingly, it is again the public interest that primarily dictates when a breach of the duty is justified,<sup>139</sup> given that this is not an absolute duty.<sup>140</sup> Several cases arising from the medical context show how the public interest actually functions in this twofold manner. I will briefly refer to some of these

<sup>134</sup> For these principles see mainly *Attorney General v. Guardian Newspapers, (No. 2)* [1990] AC 109. It is interesting to notice here that the exact legal basis of the duty of confidentiality is fraught with ambiguity: for an introduction to this theoretically puzzling question, see G.T. Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University Press, 2002), pp. 215-218 and for a much more detailed analysis R.G. Toulson and C.M. Phillips, *Confidentiality* (London: Sweet & Maxwell, 1996), chapter 2.

<sup>135</sup> This duty is equated with the right of the patient not to have information about her disclosed to the public without her consent.

<sup>136</sup> For an analysis of what information has the "necessary quality of confidence", see the reasoning in *Coco v. A.N. Clark (Engineers)* [1969] RPC 41.

<sup>137</sup> See GMC, *Confidentiality* (London: GMC, 2004).

<sup>138</sup> See the speech of Lord Goff in *Attorney General v. Guardian Newspapers, (No. 2)* [1990] AC 109 at 281B-C and also the apposite reasoning in the similar Scottish case *Lord Advocate v. Scotsman Pub. Ltd* 1989 SLT 705. Yet, the decision in the more recent *R v. Department of Health, ex parte Source Informatics Ltd* [2000] 1 All ER 786, seems to shift the focus of the justification towards the notion of the fairness of use of the relevant information. For a critique of this case, see G.T. Laurie, 2002, pp. 225-228.

<sup>139</sup> It goes without saying that the consent of the patient (the person towards whom the duty is owed) releases the doctor from the obligation of non-disclosure.

<sup>140</sup> As it was explicitly stated in *Woolgar v. Chief Constable of Sussex Police* [1999] 3 All ER 604, CA.



cases, aiming primarily on the conditions that justify a breach of the duty, since this is the area that seems to be more problematic.

*X v. Y*<sup>141</sup> referred to the disclosure to the public, through the press, of the information that two general practitioners were suffering from AIDS. This information was revealed to a newspaper by an employee of the health authority. The health authority sought an injunction against the identification of the practitioners, while the defendants argued that disclosure was justified, given that it is in the public interest to know that health care professionals suffer from such a disease. Rose J took the view that while there was a public interest in the maintenance of public health as well as a public interest in the freedom of the press, in this particular case none of them justified the breach of the duty of confidentiality,<sup>142</sup> which is itself established in the public interest. Insisting on the difference between "what is interesting to the public and what is in the public interest to make known"<sup>143</sup> the judge granted the injunction. The conclusion was different in *W v. Egdel*,<sup>144</sup> a case referring to the disclosure of confidential information by the psychiatrist of a mentally ill prisoner. This information, in essence the conclusion of the doctor's assessment of the dangerousness of W, was acquired during the process of W's psychiatric evaluation pending his application for transfer to a different secure unit.<sup>145</sup> The Court of Appeal held that the breach of the duty was in these circumstances justified, given that the protection of the public from dangerous individuals merits (as an obvious demonstration of the public interest) the overcoming of the (equally public in nature)<sup>146</sup> interest to have confidences maintained.

Leaving the factual content of these cases aside, what is interesting to observe is that the courts do not attempt to develop a set of standard criteria to substantiate the public interest exception. Rather, they tend to argue in an *ad hoc* manner that solely aims at examining whether the breach of the duty was justified in the particular circumstances of the case they hear.<sup>147</sup> Although it has been argued that a common theme, namely the

<sup>141</sup> *X v. Y* [1988] 2 All ER 648.

<sup>142</sup> More precisely he argued that public health was not under threat given the facts of the case and that the public interest in the freedom of press was not in the circumstances so strong as to justify the breach of the duty.

<sup>143</sup> 2 All ER 648, at 658d-661g.

<sup>144</sup> *W v. Egdel* [1990] 1 All ER 835, [1990] 2 WLR 471, 4 BMLR 96, CA.

<sup>145</sup> For a rather similar case that refers to the custodial disposal of a prisoner and manifests a similar outcome, see *R v. Crozier* (1990) 8 BMLR 128.

<sup>146</sup> What is interesting here is that the court insisted that it is the *public* interest in maintaining confidences to be weighed against the public interest that possibly justifies the breach, and not the *private* interest of the patient involved.

<sup>147</sup> This is not necessarily the case when minors are involved, as it has been demonstrated in *Re C (A Minor) (Evidence: Confidential Information)* (1991) 7 BMLR 138 and in *Re D and another* [1995] 4 All ER 385. In this context, the concept of the public interest tends to be linked with the best interests principle, in the sense that serving the best interests of the minor is always in the public interest; this of course, brings us back to the well-known problem of defining what is in the best interests of the minor!

avoidance of harm,<sup>148</sup> may be traced, it remains the case that the courts prefer a particularistic approach. In this respect, ambiguity remains a feature of the law of medical confidentiality and hence future developments must be seen as quite unpredictable.<sup>149</sup>

With this brief reference to the law of medical confidentiality, I have concluded the exploration of the most important norms emanating from case law. In the next section I will take on board the legislative provisions. The structure of this presentation is twofold: first, I will discuss norms that deal with some particular instances of medical practice, namely those that have attracted much scholarly interest so far. Then, I will focus my attention on the regulation of the administration of health care provision in the UK.

## 2) Legislation.

### a) Subject-specific legislation.

#### *i. Mental health.*

The regulation of the management of patients suffering from mental health problems acquires particular significance, mainly because in a rather intuitive manner the stakes in this field are (or seem to be) unusually high. For a variety of reasons that arguably include the conceptual unease about the very notion of mental health,<sup>150</sup> the untreatable character of some conditions,<sup>151</sup> the possible dangerousness of patients for the public at large<sup>152</sup> and the very real tradition of compulsory detention of mental health patients in specially designed institutions, it seems that mental health is a special issue that requires exceptional regulatory responses. Indeed, legislation pertaining to mental health has been around for quite some time<sup>153</sup> and still remains at the centre of a heated public debate. At the time of writing a new bill aiming at reforming the current system is under scrutiny<sup>154</sup>

<sup>148</sup> For this point, see G.T. Laurie, 2002, p. 230.

<sup>149</sup> For further analysis of this problem, with an emphasis on the administrative bureaucracy of the NHS that has an important effect on this ambiguity, see J. Montgomery, 2003, pp. 277ff.

<sup>150</sup> For a classic radical view see T. Szasz, *The Manufacture of Madness* (New York: Harper and Row, 1972).

<sup>151</sup> For a short discussion of the significance of this issue, see J.K. Mason and G.T. Laurie, 2005, p. 717 with further references.

<sup>152</sup> The popular perception of the mental health patient as a potentially dangerous individual is indeed quite strong, although it seems that this is probably a misrepresentation of reality. For an introduction to the issue, see P.J. Taylor and J. Gunn, "Homicides by People with Mental Illness: Myth and Reality" (1999) 174 *British Journal of Psychiatry* 174.

<sup>153</sup> For instance, for the period after the World War II, the first relevant statute has been the Mental Health Act 1959.

<sup>154</sup> This is the draft Mental Health Bill 2004.

and it seems that the government's intention is to pass this new legislation in the near future. However, this is not the case yet and as a previous version of this bill has already been withdrawn after having faced severe criticism,<sup>155</sup> I will only discuss here the legislation as it now stands.

Currently, the relevant regulation is included in the Mental Health Act 1983 for England, Wales and Northern Ireland and in the Mental Health (Care and Treatment) (Scotland) Act 2003 for Scotland.<sup>156</sup> Both these Acts must be read in the light of the Human Rights Act 1998, given that many aspects of the management of mental health may possibly raise issues of human rights infringements.<sup>157</sup> Their exact provisions are quite complicated, since they regulate in a very detailed manner both substantial and procedural issues. Here, I will refer only to the most significant provisions.

The 1983 Act mainly deals with the regulation of the *compulsory detention* of patients suffering from mental health problems. This is just one possibility from within a range of options regarding the management of such patients. Other alternatives include care in the community and voluntary hospitalisation, but these are not essentially covered by the Act. Compulsory detention is addressed according to a twofold distinction: section 2 of the Act regulates the so-called "compulsory detention for assessment". This detention that cannot extend a 28-day period aims at detecting whether the patient suffers from a mental disorder included in section 1 of the Act. If this is the case, then, according to section 3, the patient is detained in hospital in order to be treated. The precondition of such a detention is that treatment is deemed to be necessary for the health and safety of the patient or the protection of others, that treatment cannot be provided without detention and that two doctors have certified that the patient suffers from mental illness, severe mental impairment and psychopathic disorder. There is a time limit of six months for such a detention, but this can be extended if an application is made to the Mental Health Act Commission, which is also established by the Act, under section 121.

The most important feature of these provisions is that during the period of the compulsory detention the patient can be lawfully treated for the mental disorder on the basis of which she is kept in hospital, *without* her consent.<sup>158</sup> This is explicitly provided in

<sup>155</sup> This was the Mental Health Bill 2001.

<sup>156</sup> Which repealed the Mental Health (Public Safety and Appeals) (Scotland) Act 1999, interestingly the first Act passed by the Scottish Parliament.

<sup>157</sup> Indeed, cases have been heard on the basis of human rights violation. For a discussion of some of them, see J.K. Mason and G.T. Laurie, 2005, p. 725.

<sup>158</sup> This exception only applies to treatment of this particular condition; for any other condition, the general law of consent applies.

Part IV of the Act, especially by section 63, in terms of which a patient's consent is not required. The problem here is to clarify what exactly constitutes "treatment" for a mental disorder. This issue has been addressed by the courts; the general trend is to perceive such a treatment in a very wide sense and to include therapeutic measures that not only directly affect the condition of the patient, but also benefit her indirectly. Just to provide some examples, it has been held that feeding in cases of anorexia nervosa belongs to treatment under section 63;<sup>159</sup> also, that a caesarean section performed against the wishes of a pregnant woman suffering from schizophrenia was to be understood as treatment of her mental condition.<sup>160</sup> In both cases the result was that this treatment could be lawfully administered without consent. Yet, within the Act exceptions are present. Section 57 provides that when surgical procedures that destroy brain tissue or its function are involved or when hormone implants that reduce male sex drive are to be used, the patient must consent and the treatment must be further supported by a second medical opinion apart from the doctor in charge. Additionally, according to section 58 of the Act the patient's consent is necessary when electro-convulsive therapy is involved, unless a second medical opinion supports this treatment.

The Scottish Act parallels the 1983 Act in that it also refers to different stages in the process of detention. A distinction is made between "emergency detention", "short term detention" and "compulsory treatment" and similar time limits are introduced. However, two significant differences must be mentioned. First, this Act includes a more comprehensive definition of what constitutes mental disorder for its purposes: in section 328, this is defined as any mental illness, personality disorder or learning disability. Secondly, the 2003 Act is very much in favour of a community care philosophy: therefore, and in combination with Mental Health (Patients in the Community) Act 1995 it provides for out-patient treatment with the assistance of the social services.

## *ii. Reproduction.*

Although the field of human reproduction raises a very wide range of issues that call for medical and legal intervention, I will confine my discussion here only to three apposite statutes. The first is the Abortion Act 1967, the provisions of which designate the lawfully performed abortions. The second is the Human Fertilisation and Embryology

<sup>159</sup> See *SW Hertfordshire HA v. KB* [1994] 2 FCR 1051 (FD).

<sup>160</sup> See *Tameside & Glossop Acute Services Trust v. CH* [1996] 1 FCR 753.

Act 1990,<sup>161</sup> which advances a detailed regulatory framework for the activities that currently give content to assisted reproduction. The last one is the Surrogacy Arrangements Act 1985 that regulates some issues arising from the practice of surrogate motherhood. It goes without saying that these statutes do not exhaust all the legal perplexities of the regulation of reproduction; yet, they do constitute a comprehensive starting point.

The Abortion Act 1967, as amended by the 1990 Act, includes a number of reasons on the basis of which a termination of pregnancy is lawful.<sup>162</sup> The list of reasons obeys a basic time-related distinction, namely whether the termination of pregnancy happens before or after the 24<sup>th</sup> week of gestation. If the 24<sup>th</sup> week is not exceeded, then an abortion is lawful if it is performed by a registered medical practitioner and two register medical practitioners are of the opinion that the continuation of pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman, or any existing children of her family (section 1(1)(a)). This reason does not apply after the 24<sup>th</sup> week of pregnancy. All the other reasons included in the Act do not depend on this temporal restriction. These include the risk of a grave permanent injury to the physical or mental health of the pregnant woman (section 1(1)(b)); the possibility that the continuation of pregnancy would involve risk to the life of the pregnant woman greater than if the pregnancy were terminated (section 1(1)(c)); finally, the substantial risk that, if the child were born, it would suffer from such physical or mental abnormalities as to be severely handicapped (section 1(1)(d)). When any of these reasons holds a termination of pregnancy is lawful and it can be performed in any NHS hospital or other place approved for such a use. As a general comment, it can be said that these reasons are so widely drafted that for any practical purpose abortion is unquestionably lawful in the UK, especially during the first 24 weeks of pregnancy. However, the way that the Act is drafted does not provide women with a “right” to abortion, but only with a set of reasons that legalise the practice. This in turn means that in essence, whether an abortion will be performed or not, is a matter of a complete discretion of the doctor in charge; the Act simply absolves doctors from criminal responsibilities if one of the defences holds.

The HFE Act 1990 is a very detailed piece of legislation that was drafted as a result of the realisation that medical advances in the domain of reproduction have

<sup>161</sup> From now on, I will refer to this Act as the HFE Act 1990.

<sup>162</sup> In purely legal terms, these reasons constitute legal defenses against offences that exist at the background of the Abortion Act 1967, and are mainly included in the Offences Against the Person Act 1861 and the Infant Life Preservation Act 1929 (although the relevant provisions of the latter have been repealed by the HFE Act 1990).



radically altered a field that was traditionally outside the scope of the law. A detailed account of the provisions of the Act is beyond the purposes of this chapter,<sup>163</sup> so I will only refer to its underlying principles. The main tenet of the Act is the establishment of a system of licensing referring to the legality of a range of medical techniques and activities that are now performed due to scientific developments in medicine. In charge of this licensing scheme is the Human Fertilisation and Embryology Authority, that supervises any activity regulated by the Act and informs the Secretary of State for Health whenever it deems this to be appropriate. As far as reproduction is concerned, any clinic or other institution that provides treatment related to assisted reproduction, which involves technical activities outside the body, must operate under a license given by the Authority. Without such a licence, the use or storage of gametes or the creation of an embryo outside the human body is prohibited. In addition to this basic provision, a set of activities that include the placing in a woman of any live gametes or embryos other than those of human origin, the placing of a human embryo in any animal, the replacement of an embryonic nucleus by a nucleus taken from a cell of any other person or embryo and the keeping or using of an embryo after the 14<sup>th</sup> day of its existence cannot be licensed in any case and therefore are completely prohibited. Furthermore, the Authority is to draft and maintain a Code of Practice that must provide guidance as to how the clinics that perform licensed activities are to function.

In addition to these general provisions, the HFE 1990 incorporates a variety of detailed norms that regulate concrete issues arising within assisted reproduction.<sup>164</sup> However, because of the rapid pace of scientific developments in the field, even the 15-year-period from the passing of the Act has necessitated a reassessment of the regulatory regime. At the time of writing, a process of re-evaluation of the 1990 Act is in place, although its desired effect is still unclear. The House of Commons Science and Technology Committee has already published a relevant report<sup>165</sup> and a further consultation document is apparently imminent.

Let me conclude this section by a brief mention of the Surrogacy Agreements Act 1985. The main thrust of this Act is to prohibit surrogacy agreements on a commercial basis. This fundamental provision does not entail that the necessary costs for the benefit of the surrogate during pregnancy are not to be paid, but only that explicitly

<sup>163</sup> Probably the most detailed account of the provisions of the Act can be found in R.G. Lee and D. Morgan, *Human Fertilisation and Embryology Act 1990* (London: Butterworths, 2001).

<sup>164</sup> For a detailed analysis of the most important provisions, see J.K. Mason and G.T. Laurie, 2005, pp. 74ff.

<sup>165</sup> The House of Commons Science and Technology Committee Fifth Report, *Human Reproductive Technologies and the Law* (2005, available at [www.parliament.uk/s&tcom](http://www.parliament.uk/s&tcom)).

commercial transactions are out of the picture. This is further reinforced by section 36 of the HFE Act 1990, that added a provision in the 1985 Act, according to which no surrogacy agreement is enforceable by or against any person included in the making of it. Accordingly, although surrogacy agreements are as such lawful their ultimate result is not necessarily the one that the parties intended.

### *iii. Organ donation and transplantation.*

The legal regulation of organ donation and transplantation is based on two fundamental distinctions. The first refers to the source of the organ or tissue that is donated; in this respect, one can distinguish between *xenotransplantation*, where organs are transferred from one species to another and *homotransplantation*, where the transfer involves only human beings. Since at the moment the Xenotransplantation Interim Regulatory Authority<sup>166</sup> has imposed a moratorium on relevant clinical trials, based on the need of further research on the issue, I will deal here only with homotransplantation.<sup>167</sup> Here a second distinction is crucial, one that refers to the status of the (human) donor; one can distinguish between donations from a living person and “cadaver” donations. This distinction is essential, both in terms of the technical aspects of the process and in terms of the exact legal regulation. That is why it will provide the structural backbone of this section.

“Live” donations are primarily regulated by sections 32-33 of the Human Tissue Act 2004 that has repealed the Human Organ Transplants Act 1989 in England, Wales and Northern Ireland, but not in Scotland. The 2004 Act stipulates that it is an offence to perform such transplantation of this type not in accordance with specific regulations; since such regulations are not yet in place, the relevant regulations under the 1989 Act are still valid. As these are oriented to the 1989 Act, the main features underlying this Act also remain quite significant. Generally speaking, the regime is characterised by two main considerations. To begin with, both Acts<sup>168</sup> prohibit the giving or receiving of any financial rewards for the purpose of organ donations, in an attempt to explicitly integrate a policy against the commercialisation and commodification of human organs.<sup>169</sup> The

<sup>166</sup> This Authority has been established with the aim to monitor scientific progress on the matter, until the emergence of primary legislation.

<sup>167</sup> For a concise introduction to the most significant issues regarding xenotransplantation, see J.K. Mason and G. T. Laurie, 2005, pp. 478-481 with further references.

<sup>168</sup> In section 32 of the 2004 Act and in section 1(1) and (2) of the 1989 Act.

<sup>169</sup> It has to be stated though that this line of thought is not uncontested. For the opposite arguments, see amongst others A.S. Daar, “Paid Organ Donation – the Grey Basket Concept” (1998) 24 *Journal of Medical Ethics* 365 and

second consideration is to be found in the 1989 Act. This prohibits transplantation between persons that are not genetically related (as this is defined in section 2(2) of the Act), unless this is authorised by the Unrelated Live Transplant Regulatory Authority;<sup>170</sup> this provision leaves transplantation between genetically related individuals to be regulated by the common law and essentially by the doctrine of consent.<sup>171</sup> Authorisation depends on several factors, the most important of which is the lack of any element of commercialisation, the consent of the donor and the counselling of both parties.<sup>172</sup>

“Cadaver” donations are regulated by the Human Tissue Act 2004 in England, Wales and Northern Ireland.<sup>173</sup> The Act has replaced the Human Tissue Act 1961,<sup>174</sup> which authorises the removal of organs on the basis of a specific indication of the deceased or on the decision of the person “lawfully in possession of the body”, if this person has no reason to believe, after having made such “reasonable enquiry as may be practicable”, that the deceased or any surviving relative would have objected to the donation (section 1(1)). The new Act replaces this provision, by stipulating that the use of the body or of the removed organs of a deceased person is lawful for the purpose of transplantation if this is done with “appropriate consent”, according to section 1(1)(b&c). The “appropriate” consent is the consent of the deceased person; in case that a relevant directive is absent, consent may be given by a person nominated by a living adult to act in his interests after his death (according to section 4). If this is not the case either, authority to consent is transferred to the person who stood in a “qualifying relationship” with the deceased (defined in section 27(4)). In any case, cadaver donations and transplantation fall within the ambit of the Human Tissue Authority, a crucial responsibility of which is to provide a Code of Practice regarding the procedure. The new regime emerged as the governmental response to the widespread unauthorised use of human tissues following post-mortem examination, and tackled the issue by identifying consent as the cornerstone of its lawfulness.

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L.D. de Castro, “Commodification and Exploitation: Arguments in Favour of Compensated Organ Donation” (2003) 29 *Journal of Medical Ethics* 139.

<sup>170</sup> This was established by the Human Organ Transplants (Establishment of Relationship) Regulations 1989 (SI 1989, No. 2107) and the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989, No. 2480).

<sup>171</sup> Recall, however, that no one is allowed to consent to being killed or seriously injured and some types of transplantation involve serious injuries to the donor.

<sup>172</sup> See in details the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989, No. 2480).

<sup>173</sup> It must be noticed that the purpose of the Act is not solely to regulate the issue of transplantation, but generally the use of human tissues.

<sup>174</sup> Let me stress that this Act remains in force in Scotland, along with the Anatomy Act 1984 and the Corneal Tissue Act 1986.

*iv. Medical research.*

For the purposes of this chapter, the most interesting feature of the field of medical research is the significant absence of detailed regulation. Leaving aside the provisions of the HFE Act 1990, according to which the Authority must license those activities that fall within the scope of the Act (and certain types of research are indeed covered by the Act), medical research is essentially unregulated by the legislature directly. At first glance, this seems rather odd, especially if one considers the history of atrocities that took place on the sidelines of medical research during the course of the 20<sup>th</sup> century<sup>175</sup> and the very intense media interest in anything new that is announced as a result of medical research.

The only regulatory instrument that directly deals with medical research, is the Medicines for Human Use (Clinical Trials) Regulations 2004. This instrument implements in the UK the provisions of the relevant European Directive regarding the conduct of clinical trials on medical products for human use.<sup>176</sup> Obviously, the scope of this instrument is rather narrow, since it applies only to clinical trials of medical products. Consequently, any other form of medical research is beyond the scope of this particular regime.

Nonetheless, the scarcity of direct legal regulation does not entail a total lack of control mechanisms on how research is conducted. On the contrary, a comprehensive system of “research governance” is in place. The concrete content of this system originates from two distinct institutional sources. The first is the Department of Health that provides guidance, in the form of principles, governing all medical research which is conducted within the ambit of the Department, namely within the NHS. The current guidelines are included in the Department’s publication *Research Governance for Health and Social Care*<sup>177</sup> and are primarily oriented to the notion of consent as the main premise in terms of which research can be conducted. The second institutional source of research governance is a “network” of Research Ethics Committees that also provides guidance for medical research. I use the term network to stress that there exists a variety of such Committees or similar bodies that all operate in the “soft” regulation of medical research. For instance, several NHS Trusts have formed ethics committees that participate in the relevant decision-making processes. In a more central level, Health Authorities have set

<sup>175</sup> In the international domain, codes of practice have been drafted in order to counter the possibility of such atrocities happening again. The most significant one is currently the Declaration of Helsinki drawn by the World Medical Association, as amended in 2000.

<sup>176</sup> Directive 2001/20/EC of 4 April 2001.

<sup>177</sup> Department of Health, *Research Governance Framework for Health and Social Care* (2005), available at [www.dh.gov.uk](http://www.dh.gov.uk).

official (in the sense that they have done that under the auspices of the Department of Health) Local Research Ethics Committees in order to control research that involves patients within their responsibility. These committees operate under the general control of the Central Office of Research Ethics Committees<sup>178</sup> and the UK Ethics Committee Authority, which further ensures that medical research is under a centralised system of control. In addition to these public committees, other bodies also provide guidance for research, such as private research establishments (like the Nuffield Council of Bioethics) and the Medical Research Council.<sup>179</sup>

Although this system of governance ostensibly appears as heavily bureaucratised, it constitutes an alternative structural possibility for the control of a particular aspect of medical practice. It can be said that it is more flexible, since it allows for different decisions to be made as science progresses; also, such a system is more open to a wide range of influence from several parties and this again has the advantage of a more comprehensive review of a proposed research project. Of course, these positive features constitute just one side of the story. Against such a system it can be said that it is over-complicated and that it is very difficult to achieve uniformity of standards.<sup>180</sup> In any case, it seems that as time goes on, the regime is further expanded by a proliferation of the number of committees that are being established. Therefore, it is safe to state that “soft regulation” will remain the choice regarding the control of medical research in the foreseeable future.

#### *v. Miscellaneous.*

I will conclude this part of this chapter by referring briefly to a number of statutes that have a significant impact on the regulation of medical practice. These statutes do not directly cover a particular condition or a particular aspect of medicine. Their scope is more general than medicine, but their particular provisions combine with norms emanating from case law and in this sense complete the relevant normative edifice. I will refer to three statutes: the Data Protection Act 1998, the Adults with Incapacity (Scotland) Act 2000 and the Mental Capacity Act 2005.

<sup>178</sup> It has now been subsumed under the National Patient Safety Agency.

<sup>179</sup> For a very detailed analysis of the exact regime under which all these bodies operate, see J. Montgomery, 2003, pp. 348ff.

<sup>180</sup> For a careful discussion of the pros and cons of research committees, see J. Neuberger, *Ethics and Health Care: The Role of Research Ethics Committees in the United Kingdom* (London: King's Fund Institute, 1992).



The Data Protection Act 1998 implements in the UK the relevant EU Directive<sup>181</sup> and aims at providing a regulatory regime that covers the processing of personal data. The Act refers to all personal data (that are stored either electronically or manually) that enable information about a person to be readily accessible and prohibits the “procession” of them unless certain particular conditions are met. According to section 2 (e) of the Act, health information is to be understood as “sensitive personal data”; thus, in the field of medicine, the Act complements the case-law protection of confidentiality, by further elaborating the conditions on the basis of which confidentiality can be breached in the processing of health information. These conditions correspond to a twofold level of protection. The first level is applicable to all personal data: the relevant conditions include the consent of the patient, the necessary use of the data for the patient’s “vital interests” and the necessary use of them in carrying out a governmental or statutory function.<sup>182</sup> If any of these conditions is met, then the processing of data is justified. Yet, since health information belong to the category of sensitive data the second level of protection is activated and use is authorised only if one of an additional set of conditions is also met.<sup>183</sup> These include the explicit consent of the patient, again the protection of her vital interests, the placing of the relevant data in the public domain by the patient, the need to use the data in seeking legal advice or participating in legal proceedings, again the use of the data for fulfilling governmental or statutory functions and ultimately the use of data by a health professional who is under an obligation of confidentiality for particular medical purposes (namely, preventive medicine, diagnosis, research, the provision of care and treatment and the management of health care services). In addition to these provisions the Act regulates the right of patients to have access to their records. According to sections 7&8, on the basis of a written application any patient has the right to know whether personal data are being stored and processed and also to be informed about their content in an intelligible way. This right is subject to a set of limitations, the most important of which is the likelihood of the possibility that the granting of access will cause serious harm to the physical or mental health of the data subject or any other person.

The Adults with Incapacity (Scotland) Act 2000 is a statute that deals with the general management of the affairs of incapacitated individuals. Part V of the Act refers explicitly to medical treatment and research and in this respect it complements the

<sup>181</sup> Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

<sup>182</sup> Schedules 1&2 of the Act.

<sup>183</sup> Schedules 1&3 of the Act.

common law position regarding the legality of the treatment of an incapable adult. The main tenet of the Act is that the practitioner primarily responsible for the patient has a “general authority to treat”, which must be understood as the authority to do all that is under the circumstances reasonable “to safeguard or promote the physical or mental health of the adult”.<sup>184</sup> What is interesting here is that the Act does not explicitly incorporate the best interests principle; instead, in deciding what to do the practitioner is to take into account a wide range of factors that include the previously expressed wishes of the patient, the views of relatives and other carers and the benefit of the patient. In any case, the final decision is within the discretion of the practitioner, even though the Act allows the appointment of proxy-decision makers. This is because proxies have the right only to consent to what the practitioner proposes and not to refuse. Of course, this leaves open the possibility of a dispute: in such a case, the opinion of a second medical officer appointed from a list provided from the Mental Welfare Commission provides the necessary authority for treatment or care to proceed. If the proxy still disagrees, the only option that remains open is to appeal to the Court of Session.<sup>185</sup>

Similar provisions are included in the Mental Capacity Act 2005, which refers to England and Wales. Again the main aim is to regulate the management of the affairs of the incapacitated adult, who is defined as someone who is unable to make decisions. The main difference is that the 2005 Act is explicitly oriented to the best interests principle. In effect, Part I of the Act includes a list of issues that must be considered in deciding what course of action is in the best interests of the incapable adult. Apart from that issue, the Act is very similar to its Scottish counterpart: again a proxy can be appointed to act on behalf of the incapax and be responsible for her affair (the “donee”), although the exact relationship between the donee and the doctor in charge is drafted in a more informal way.

#### **b) The regulation of health care provision.**

My intention in this part of the chapter is to provide a brief sketch of the organisation of health care provision in the UK. This sketch must necessarily be brief, mainly because both the exact structuring and the regulatory framework of health care provision are highly complex. Accordingly, a complete discussion would necessitate a completely

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<sup>184</sup> Sections 41(1) and (2) of the Act.

<sup>185</sup> For a detailed discussion of these provisions see G.T. Laurie and J.K. Mason, “Negative Treatment of Vulnerable Patients: Euthanasia By Any Other Name?” (2000) *Juridical Review* 159.

different academic project than mine.<sup>186</sup> Nevertheless, since the practice of medicine cannot be adequately understood without even a short reference to its institutional background, I will try to sum up this background in the next three sections. The first two sections are very closely connected, but I prefer to distinguish between them for reasons of analytical clarity: the first will deal with the regulatory framework that refers to the organisation of health care professions into professional bodies and the second will present the structure of the NHS, within which the health care professionals usually work. Finally, in the third section I will discuss the regulation regarding public health, since this is an issue that is always present at the background of the provision of health care within any jurisdiction but often escapes attention.

*i. The regulation of health care professionals.*

The starting point for the organisation of medicine as a profession can be traced back to 1832 through the formation of the British Medical Association (BMA). Later, in 1858 the General Medical Council (GMC) was established, which until today remains the main governing body of the medical profession. It is now regulated by the Medical Act 1983.<sup>187</sup> The main functions of GMC are to ensure that members of the medical profession are fit to practice<sup>188</sup> and to maintain an official register of medical practitioners. The upkeep of such a register is important, because although there exists no legal monopoly for medicine to be exercised solely by medical practitioners, it is an offence to pretend to be a registered practitioner. In addition to these functions, the GMC has disciplinary powers in assessing whether its members are fit to practice and in taking action whenever this is not the case. The disciplinary measures that can be taken are wide and they may include suspension or erasure from the register.

Similar bodies are in place for the oversight of other health care professionals. These are the Nursing and Midwifery Council,<sup>189</sup> the General Dental Council,<sup>190</sup> the General Optical Council,<sup>191</sup> the Council of the Pharmaceutical Society of Great Britain,<sup>192</sup> the General Osteopathic Council,<sup>193</sup> the General Chiropractic Council<sup>194</sup> and the Hearing

<sup>186</sup> For a very accurate discussion of the issue, see R. Baggott, 2004.

<sup>187</sup> Recently amended by the Medical Act 1983 (Amendment) Order 2002 (SI 2002, No. 3135)

<sup>188</sup> This function is laid down in details by the Medical (Professional Performance) Act 1995.

<sup>189</sup> Established by the Nursing and Midwifery Order 2001 (SI 2002, No. 254).

<sup>190</sup> Established by the Dentists Act 1984.

<sup>191</sup> Established by the Opticians Act 1989.

<sup>192</sup> Established by the Pharmacy Act 1954.

<sup>193</sup> Established by the Osteopaths Act 1993.

<sup>194</sup> Established by the Chiropractors Act 1994.

Aid Council.<sup>195</sup> All these bodies have similar authority to the GMC: they maintain a record of practitioners and they are to contribute to their educational preparation.

Against this background of professional bodies, a new watchdog has been established under the National Health Service Reform and Health Care Professions Act 2002. This is the Council for the Regulation of Health Care Professionals,<sup>196</sup> which has the authority to control the other regulatory bodies and to influence the way that they perform their functions.<sup>197</sup> In effect, the establishment of this Council constitutes a second level of control, with the aim of achieving unifying impact on the particular policies of each one of the individual bodies within its remit. This is most clearly demonstrated by the authority of this Council to scrutinise the disciplinary decisions of the first order bodies and to appeal against them to the High Court. It may do so because its underlying justification is the protection of the patients and other members of the public against unfit health care professionals. In this respect, it seems that the creation of this Council has added a further dimension of control that goes beyond medical self-regulation. As such it has not been very well received from the medical establishment, although the new Council is an independent body.<sup>198</sup>

## *ii. The structure of the NHS.*

In order to understand the exact structure of the NHS, it is indispensable to keep in mind that its current state represents the outcome of a long political process that started with the inauguration of the system in 1948 by the then labour government. In the course of the 60 years since then, different governments and more importantly different political parties have all contributed to what the NHS is today.<sup>199</sup> It is probably this constant political input that has determined the complex nature of the system and the simultaneous presence of different (and sometimes contradictory) ideas and policies.

From a legal point of view, the UK government is under an international obligation to provide a health service to those that are sick and without adequate resources to secure health assistance for themselves. This is firmly provided by the European Social Chapter (article 13). This governmental obligation is fulfilled through the establishment and the regulation of the NHS, which in effect constitutes a

<sup>195</sup> Established by the Hearing Aid Council Act 1968 and the Hearing Aid Council (Amendment) Act 1989.

<sup>196</sup> Recently it has been renamed as the "Council for Healthcare Regulatory Excellence".

<sup>197</sup> For further discussion, see its assessment in S. Dewar and B. Finlayson, "Regulating the Regulators" (2002) 324 *BMJ* 378.

<sup>198</sup> For a relevant discussion, see J.K. Mason and G.T. Laurie, 2005, pp. 19ff.

<sup>199</sup> For a historical account, see R. Baggott, 2004, pp. 88ff.

comprehensive system of health care delivery, which is available to all and which is not based on the ability to pay at the point of delivery. A wide number of statutes and statutory instruments regulate in detail how the service is organised and operates; also, a number of essentially political publications exhibit the aspirations of the government of the day regarding what the NHS is supposed to achieve.<sup>200</sup> Currently, these aspirations can be found in the governmental NHS Plan,<sup>201</sup> which insists on a number of targets referring to the quality of service and to the minimisation of waiting times and which crucially advances the idea of the gradual intensification of the role played by the private sector in several aspects of the NHS.<sup>202</sup> This idea has been already been substantiated in a number of statutory provisions.<sup>203</sup>

Currently, the NHS is organised in a tripartite structure.<sup>204</sup> At the top of this edifice is the Department of Health, the authority of which is defined by the National Health Service Act 1977. According to this Act, the Secretary of State for Health is obliged to promote a comprehensive health service to secure improvements in the physical and mental health of the people of England and Wales and in the prevention, diagnosis and treatment of illness. The Act does not define what illness means and allows for a very considerable range of discretion. Part of this discretionary framework is the option to combine health services with social care services and as a matter of fact a number of statutes materialise this possibility in a very detailed manner.<sup>205</sup> In effect, the Department of Health is responsible for policy making and for the centralised planning of the whole edifice of the NHS.

The second level of the structure is occupied by the Strategic Health Authorities. These have been introduced by the NHS Reform and Health Care Professions Act 2002 and in essence have taken the intermediate place that Health Authorities used to occupy according to the Health Authorities Act 1995. The main responsibility of these authorities is to provide local leadership to all the authorities of lower level that exist

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<sup>200</sup> This is important because it is rather difficult to discern a clear function or purpose for the NHS. For a discussion of this issue, see D. Seedhouse, "Does the National Health Service have a Purpose?" in A. Grubb (ed.), *Challenges in Medical Care* (Chichester: Wiley, 1992).

<sup>201</sup> For a presentation of its more important features, see R. Baggott, 2004, pp. 122-125.

<sup>202</sup> For a critique of this commitment see A.M. Pollock, *NHS plc: The Privatisation of Our Health Care* (London: Verso, 2004).

<sup>203</sup> See, amongst others, the Health and Social Care Act 2001 that allows for public-private partnerships between NHS trusts and private sector bodies to secure facilities or services under the NHS Act 1977.

<sup>204</sup> Recall that because of devolution arrangements the organisation of the NHS in England is different from that in Scotland and Wales. My discussion here refers to the English structure; for the other two jurisdictions, see R. Baggott, 2004, pp. 109-110 with further references.

<sup>205</sup> See, amongst others, the NHS and Community Care Act 1990, as amended by the Health Act 1999 and by the Health and Social Care Act 2001; also, the Chronically Sick and Disabled Persons Act 1970 and the Disabled Persons (Services Consultation and Representation) Act 1986. For further analysis of their provisions see J.K. Mason and G.T. Laurie, 2005, pp. 444-448.



within the geographical area that they control. This responsibility refers to the delivery of the targets incorporated in the NHS Plan and crucially to the quality of health care services within their particular area.

The third level of the NHS is occupied by a number of institutions that perform different functions. Primary Care Trusts, regulated by the 2002 Act and by the Primary Care Trusts (Membership, Procedure and Administration Arrangements) Regulations 2000 (SI 2000, No. 89) have a managerial function. They are responsible for commissioning actual health services locally. The local providers are the NHS Trusts,<sup>206</sup> which are responsible for providing goods and services (usually of secondary and tertiary nature), and individual general practitioners that are responsible for the delivery of primary services. These practitioners are in a contractual relationship with the NHS for the delivery of their services.<sup>207</sup> In addition, Care Trusts also belong to the same level and they are responsible for the provision of a combination of health and social services.<sup>208</sup>

Within such a complicated structure, the most significant issue is to ensure the quality of the services provided. This is usually referred to as the problem of "accountability". In effect, two main mechanisms are in place to guarantee quality of service.<sup>209</sup> The first is the clear drafting of guidelines regarding what standards of care are to be achieved. The body responsible for this is the National Institute of Clinical Excellence (NICE). This is an independent body the aim of which is to create unified standards for the NHS across the country.<sup>210</sup> It does that by developing particular models of care related to specific domains of care, widely known as "national service frameworks". These models of care incorporate rationing of particular treatments and proposals for financing particular drugs. It must also be noticed that NICE collaborates with the National Care Standards Commission, which is responsible for overseeing the provision of health care in the private sector.<sup>211</sup>

The second mechanism is the incorporation into the structure of several detailed procedures that allow patients to launch complaints against the service they have

<sup>206</sup> These are regulated by the NHS and Community Care Act 1990 and a number of statutory instruments that include the NHS Trusts (Membership and Procedure) Regulations 1990 (SI 1990, No. 2024)

<sup>207</sup> The general terms of these contracts are included in NHS (General Medical Services) Regulations 1992 (SI 1992, No. 635), NHS (General Ophthalmic Services) Regulations 1986 (SI 1986, No. 975), NHS (General Dental Services) Regulations 1992 (SI 1992, No. 661) and in the NHS (Primary Care) Act 1997.

<sup>208</sup> Care Trusts are regulated by the Health Act 1999 and the Social Care Act 2001.

<sup>209</sup> It has to be stressed that this is a very simplified account of the situation. For a much more detailed analysis, see R. Baggott, 2004, pp. 213-244.

<sup>210</sup> NICE came into existence due to the National Institute of Clinical Excellence (Establishment and Constitution) Order 1999 (SI 1999; No. 220) and the National Institute for Clinical Excellence Regulations 1999 (SI 1999, No. 260).

<sup>211</sup> In accordance with the Care Standards Act 2002.

received.<sup>212</sup> These procedures are mainly regulated by the Hospital Complaints and Procedure Act 1985; they run in parallel with the disciplinary procedures that are available from the particular procedural bodies that a health care professional belongs to.

Finally, two independent bodies are also responsible for ensuring the quality of services provided. The first is the Healthcare Commission that has very extensive powers in ensuring the effectiveness and efficiency of the health care services and is authorised to provide information and advice to health authorities and trusts.<sup>213</sup> The second is the Health Commissioner who has the authority to investigate any complaint that patients may raise.<sup>214</sup>

### *iii. The regulation of public health.*

The most interesting feature of the legislation regarding public health is its rather quaint character. Indeed, the statutes that deal with the control of infectious diseases and more generally with the response to health threats to the community are quite old and rarely thought of, although they may raise significant concerns, especially from a human rights perspective.<sup>215</sup> In a sense this appears paradoxical, given the parallel trend in emphasising the communal importance of health and healthy lifestyles – a political strategy that is of obvious significance for the health of the community.<sup>216</sup> Nevertheless, the direct regulation of public health remains sparse.

One has to start with the National Assistance Acts of 1948 and 1951. These especially refer to the removal of infected individuals to hospitals, more importantly of those individuals that cannot care for themselves. The regulation essentially amounts to compulsory care, an option that is usually allowed only for patients with particular mental health problems. More recently, the Public Health (Control of Diseases) Act 1984 creates a number of criminal offences regarding the so-called notifiable diseases, namely these diseases that a registered medical practitioner is under a legal duty to report to the relevant Authority. Initially the Act included a list of five notifiable diseases,<sup>217</sup> but later this list was expanded by the Public Health (Infectious Diseases) Regulations 1988 (SI

<sup>212</sup> The exact framework is very complicated; for a detailed analysis, see J. Montgomery, 2003, pp. 112ff.

<sup>213</sup> The Commission is regulated by the Health Act 1999 and the NHS Reform and Health Care Professions Act 2002, in combination with the Commission for Health Improvement (Functions) Regulation 2002.

<sup>214</sup> Regulated by the Health Service Commissioners Act 1993, as amended in 1996 and 2000.

<sup>215</sup> It is implied here that the relevant legislation must now be read in conjunction with the Human Rights Act 1998.

<sup>216</sup> See, for instance, Department of Health, "Choosing Health: Making Healthier Choices Easier" (2004), available at [www.dh.gov.uk](http://www.dh.gov.uk) and recall the gradual intensification of the campaign against smoking.

<sup>217</sup> Namely cholera, plague, relapsing fever, smallpox and typhus.

1988, No. 1546). The 1984 Act incorporates a set of measures that may be taken against individuals suffering from a notifiable disease: these measures include the removal of the patient from her usual place of residence, the isolation of the patient, the compulsory detention of the patient in a medical establishment and the compulsory vaccination of the patient. Interestingly, HIV infection is not considered to be a notifiable disease and therefore the 1984 Act is not of direct relevance.<sup>218</sup> However, according to the AIDS (Control) Act 1987, Health Authorities and NHS Trusts are obliged to provide reports and information to the Secretary of State for Health regarding statistics on positive HIV tests, on the number of persons actually suffering and having died from AIDS and on the relevant facilities and services they provide.

Obviously, there exists concern whether this legislative apparatus can be successful in dealing with health threats in modern times. Yet, it does not seem that any new measures are at the moment ante portas. The only exception has been the establishment of the Health Protection Agency by the Health Protection Agency Act 2004. This body is in charge of centrally identifying and taking action against any infectious disease or more generally health hazard that may be detrimental for the community, although what it can do is still under the auspices of the legislation presented in the previous paragraph.

#### **D. The modus operandi of the courts: models of judicial reasoning.**

In this penultimate part, I will direct my attention again to the judicial terrain. My intention is not to explore once more the legal norms generated by the judiciary, since I have already done that in section (C). What I will do here is to investigate the reasoning that the courts employ when adjudicating in medical cases. To put it more accurately, I intend to focus on types of arguments that are used in reasoning and through them to observe how decision-making unfolds: accordingly, it will be the mode of the reasoning that will interest me, not its substance. The reason for doing this refers again to the initial question of my thesis. My claim here is that not only the content of the relevant legal norms, but also the way that these are used is important in determining what the law can achieve in the context of medicine. From this perspective, I will intend to argue that different models of reasoning can be detected and that this in itself is significant insight for understanding the orientation of law to medicine.

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<sup>218</sup> Nevertheless, specific powers of detention of HIV/AIDS patients are included in the 1988 Regulations.

In order to do that, I will discuss the reasoning in five cases, which I will use as short case studies. My analysis will be conducted with the help of a range of theories of legal reasoning, chosen because of their compatibility with the particularities of the decision in each case. I am aware of course that this methodology is liable to the criticism that the selection of both the cases and the theories is arbitrary and therefore any conclusions that may be reached essentially unfounded. However, the cases I am presenting incorporate a variety of medical disputes and have been decided by courts belonging to different levels of the judicial hierarchy and at different moments in time; accordingly, it seems to me that they are quite representative of the field. Also, I must insist that my reading of these cases in terms of particular theories that advocate (either descriptively or normatively) one model of reasoning at the expense of any another does not imply that this is the only possible way that these cases may be analysed. I totally accept that alternative readings are also possible. Still, I believe that this further justifies the point that traces of different models of reasoning are present in the case law. The choice of a particular theory as a point of observation simply helps to identify some of these traces; it does not follow that everything is in that way revealed.

### 1) *Re C (adult: refusal of medical treatment)*.<sup>219</sup>

The facts of this case, decided by Thorpe J, are rather straightforward. The patient involved, a 68-year-old man, was suffering from chronic paranoid schizophrenia. In September 1993, he was diagnosed with gangrene in the foot and for this reason he was transferred to Heatherwood Hospital. After a period of testing and consultation, it was concluded that the patient would die imminently if the leg were not amputated below the knee, and that the chances of survival if more conservative treatment were administered were very low. However, the patient refused to accept amputation and insisted on his refusal even though pressure was applied on him to consent. Accordingly, an injunction under the court's inherent jurisdiction was sought, restraining Heatherwood Hospital from amputating his right leg without his express consent.

Thorpe J granted the injunction sought. He approached the issue in terms of the law of consent, according to which the legality of any medical intervention on an adult patient capable of consenting depends on his or her actual consenting to the intervention. Given that the patient refused to give his consent, it was his capacity to do

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<sup>219</sup> *Re C (adult: refusal of medical treatment)* [1994] 1 All ER 819.

so that was primarily questionable. The judge held that the patient was indeed capable to give or refuse consent, that his refusal was for this reason valid and that, accordingly, he was obliged to grant the injunction, although there was a possibility that this could lead to the death of the patient.<sup>220</sup> Focusing on capacity to consent, he argued that this is a relative concept that depends on the nature, purpose and effect of the medical procedure involved and not on the general state of the patient.<sup>221</sup> He further expanded this argument by proposing a three-stage test regarding the assessment of this relative capacity to consent which includes the ability of the patient to comprehend and retain the necessary information; to believe this information; finally, to weigh the information by balancing risks and benefits so as to arrive at a choice.<sup>222</sup> Thorpe J was persuaded that given the proven facts of the case the test was satisfied and thus the patient was capable to consent or refuse the proposed amputation.

As far as the reasoning underlying this decision is concerned, it seems to me that this is a clear example of what is generally described as *formal reasoning* based on *deductive justification*.<sup>223</sup> Thorpe J justifies his decision through the direct application of a legal norm (that the consent of a capable adult is always required for the legality of a medical intervention) that both classifies what aspects of the facts are relevant (namely the refusal to consent and the question of capability) and serves as the major premise for a conclusion (that the injunction should be granted) based on deduction. Of course, in the course of the justification of the conclusion, the capacity issue must be resolved; indeed, it is the dispute regarding the capacity of the patient that constitutes the main legal dispute of the case. However, this problem is again framed in terms of the initial legal rule regarding consent. Thorpe J is ready to accept as a general presumption that any adult patient is autonomous and thus capable to decide, on the basis of a general right of self-determination; then, he formulates the test of capacity as a means that substantiates this presumption and that designates the conditions for the possibility of a particular patient to be excluded from the presumption (when in a particular scenario the test is not satisfied). The very formulation of the test is not in itself arbitrary: it is based on a similar proposal of the Law Commission at the time,<sup>224</sup> which again presumes that

<sup>220</sup> As it turned out the patient survived even without having the leg amputated.

<sup>221</sup> This implies that for the particular stake of the case, the fact that the patient suffered from schizophrenia was irrelevant as such.

<sup>222</sup> See [1994] 1 All ER 819, at p. 824.

<sup>223</sup> Although the relevant literature is vast, an excellent analysis can be found on N. MacCormick, 2005, pp. 33ff.

<sup>224</sup> Thorpe J quotes the consultation paper 129 of the Law Commission, entitled *Mentally Incapacitated Adults and Decision-Making*, especially paragraph 2.20.



capacity to decide exists and that it can be displaced only on the basis of a negative assessment in terms of the test.

Within this framework, one could classify this case as a *clear case*, namely a case that generates no essential dispute about the relevant facts or the applicable law.<sup>225</sup> The relevant theorising insists that decisions in clear cases are justified (and also should be justified) in terms of a deductive syllogism that treats the relevant legal rule as its major premise and provides justification exactly because of its logical strength. Indeed, it seems that this is exactly the path that Thorpe J is following here: he reaches his conclusion through a deduction based on the application of the relevant legal rule to the pertinent facts.<sup>226</sup> That is why external factors that could have an impact on the decision (for instance the dangerousness of the refusal for the health of the patient) were excluded from consideration. Deductive justification is essentially characterised by a certain closure: since this is a form of justification based on logic, only what falls within its syllogistic schema is and should be considered.

## 2) *Sidaway v. Bethlem RHG (HL)*.<sup>227</sup>

This is probably one of the most widely analysed cases regarding the law of consent. The dispute arose because Mrs Sidaway was left partially paralysed after an operation to free a trapped nerve. This outcome was due to the fact that the patient suffered injury to her spinal cord during the operation. However, its occurrence was not attributable to any negligent mistake in the way that the operation was performed; rather, it was the result of the unfortunate materialisation of a risk inherent in similar operations. The possibility of a claim of usual negligence having been excluded, Mrs Sidaway brought an action claiming that she had not been informed about the risk and that had she known about it she would have refused to agree to the operation. This was again a claim of negligence, but the alleged negligence referred to the process of communication between Mrs Sidaway and her doctors.

<sup>225</sup> For the term “clear case”, I will refer again to N. MacCormick, 2005, chapter 3; see also, J. Raz, *The Authority of Law* (Oxford: Clarendon Press, 1979), pp. 181ff., although he prefers the term “regulated” cases and reaches slightly different conclusions. For the opposite view, namely that this particular type of case simply does not exist, see amongst others M. Kelman, *A Guide to Critical Legal Studies* (Cambridge, Mass.: Harvard University Press, 1987), pp. 4ff.

<sup>226</sup> In this respect, the value of discussing this case is exactly in showing that at least in clear cases a deductive syllogism is part of legal reasoning.

<sup>227</sup> *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All ER 643, [1985] AC 871, [1985] 2 WLR 480, 1 BMLR 132, HL.

Her claim failed at all judicial levels. Yet, although the outcome was the same at each level, none of the justifications proposed was similar. Especially in the House of Lords, where four judges delivered speeches, each one of them provided a different justification for his conclusion. It follows that it is necessary to take into account all the four opinions. Before continuing, let me just repeat that what we are dealing with here is the issue of substantiating the standard of care in the case of information disclosure.

Approaching this problem from a jurisprudential point of view, the claim of Mrs Sidaway's generates what it can be called a "problematised" case.<sup>228</sup> This is to be contrasted from the previously employed term "clear" case and implies that in the case at hand, it is not enough to simply apply a deductive syllogism to yield a solution: this is because one or some of the premises of the syllogism has been contested, in other words has been "problematised", by one of the parties involved. Neil MacCormick has identified four possible types of such a problematisation.<sup>229</sup> The first type can be depicted as a problem of *proof* and refers to the situation where the factual aspects of the case remain contested. The second type, depicted as a problem of *classification*, refers to the situation where it is contested whether the undisputed facts of the case should be understood as an instance of the legal norm that is to serve as the major premise of the syllogism. The third type, depicted as a problem of *interpretation*, refers to the situation where the proper interpretation of the applicable legal norms is contested. Finally, the fourth type of problem, depicted as a problem of *relevancy*, refers to the situation where it is disputed whether the ostensibly applicable norm is properly constructed as such from the existing matrix of legal norms, in the light of the particular facts of the case.<sup>230</sup>

Along these lines, it can be argued that the case I am discussing is problematised in terms of either classification or relevancy. In essence, what Mrs Sidaway argues is that the facts of her claim do not fall within the ambit of the norm that defines the standard of care (namely the *Bolam* test), because this norm refers to negligence in treatment and not in communication (a problem of classification). Alternatively, the argument could be that a norm must be constructed that would be relevant for the standard of care for negligence in communication: such a norm is not to be drafted in accordance with the

<sup>228</sup> The term "problematised" case is advanced by N. MacCormick, 2005, pp. 50ff, following the analysis in J. Bengoetxea, *The Legal Reasoning of the European Court of Justice* (Oxford: Clarendon Press, 1993), pp. 183ff. Traditionally the term that is used to describe such cases is the term "hard".

<sup>229</sup> See, in details, N. MacCormick, 2005, pp. 39ff.

<sup>230</sup> It is interesting to notice that "problematisation" thus defined is a pragmatic and not an ontological feature of cases, in other words it is totally contingent on the way that a particular judicial dispute will evolve. Once again, see N. MacCormick, 2005, p. 51 and J. Bengoetxea, 1993.

Bolam test, because such a formulation ignores the differences of the factual situation (a problem of relevancy).

Having conceptualised the case as problematised, what has to be tackled is the method that is to be used in resolving the problem, namely the exact formulation of the applicable norm. Again, this involves an argumentative process, since the outcome of this resolution has to be justified. Now, this is a different level of justification in the sense that it does not directly control the final outcome of the case but only the preliminary stage of settling the major premise. Still, this second-order justification<sup>231</sup> is equally important for the obvious reason that its outcome will be part of the final determination of the solution.

So, how is the need for a second-order justification to be addressed? MacCormick argues that this kind of justification must follow a methodology at the centre of which rests the concept of the universalisability of the consequences of the decision that is to be made.<sup>232</sup> This claim integrates three distinct tenets. First, that for a decision to be justified, its underlying logic must be universalisable, namely able to be applied in all the similar situations that may arise in the future. Second, that the general criterion that must be used in determining whether this is the case is the consequences that the application of the same solution will have in future cases; by the term consequences what is meant is “juridical consequences”,<sup>233</sup> namely the consequences that will relate to the behaviour of the judiciary in future cases. Third, that the evaluation of these consequences must not be exercised in a vacuum, but rather in a manner controlled by more elaborate criteria. The most important of these criteria is the requirement of consistency and coherence: in this context, consistency means non-contradiction with the existing body of law and coherence signifies consistency in principle with previous decisions.

Bringing this abstract theoretical edifice back to Mrs Sidaway’s case, MacCormick’s argument is that the dispute regarding the settling of the standard of care in informed consent must be resolved as follows: the court must provide a justified solution to the problem of classification/relevancy (second-order justification), the logic of which will be universally applied to all the cases of informed consent that will arise in the future. The criterion of this justification is the juridical consequences that the ruling

<sup>231</sup> For the reasons why this should be understood as second-order justification, see N. MacCormick, *Legal Reasoning and Legal System* (2<sup>nd</sup> edition, Oxford: Oxford University Press, 1993), pp. 101ff.

<sup>232</sup> In effect, this assertion is the cornerstone of N. MacCormick’s theory of legal reasoning, which is discussed in details in both his 1993 and 2005 publications. What I say here is just a simplified version of very thorough and complex theory.

<sup>233</sup> For this notion, see in details N. MacCormick, 2005, pp. 104ff.

will have for future cases, in other words the particular impact that the ruling in the case at hand will have on the way that courts will later decide similar cases. In turn, this impact has to be evaluated in terms of the requirements of consistency and coherence: accordingly, a universalisable decision must yield a result that will allow future judges not to be inconsistent (namely not to contradict established legal norms) and incoherent (namely, not to contradict well-established legal principles). Having summarised the theory in such a way let me now examine if its findings hold true in the speeches of the judges that actually decided the case.

Let me start by considering the judgement of Lord Diplock. The core of his argument is that in cases of medical negligence there is only one professional duty: this is to exercise skill and judgement with the aim of improving the patient's health. This being the case, it makes no sense to fragment this duty in accordance with particular types of medical activity. Accordingly, the usual norm regarding the standard of care should apply. By following this line of argument, Lord Diplock discards the problematisation of the case that Mrs Sidaway advocates at the outset: what he does is to counter her claim regarding classification/relevance by arguing exactly that there is no significant distinction to be made between negligence in treatment and negligence in communication. For him, this remains a clear case. The Bolam test is undoubtedly to be applied and this being so, the outcome is yielded through the implicit invocation of a deductive syllogism very similar to the one in *Re C*.

In contrast with Lord Diplock the three other judges seem to accept the problematised nature of the case at hand. This can be inferred from their attempt to reformulate the normative content of the Bolam test, in order to render it more compatible with the context of informed consent. In this respect, they are all involved in a process of second-order justification. What has to be seen is whether they do that by respecting the requirements that MacCormick advances in his theory.

Lord Scarman argues that the starting point for the delineation of the standard of care must be the right of the patient to decide about what will happen to her. In accordance with this main tenet, she has the right to be informed about any material risks that may be part of the procedure proposed. Therefore, it is the duty of the doctor in charge to inform the patient about such material risks; to this assertion, he adds that the criterion of what risk should be understood as material is the assessment that would be expected by a prudent patient facing the same procedure as the claimant. In formulating the standard of care in such a way, Lord Scarman is actually in tune with both the

requirements of coherence and consistency. He respects coherence, since his formulation cherishes the basic principle of autonomy that underlies the whole field of consent to treatment. Also, he is careful in avoiding the possibility of inconsistency: he adds the caveat of the "therapeutic privilege", namely he allows doctors not to reveal information that they reasonably believe that could have detrimental effect for the health of the patient. This caveat is in tune with the best interests principle, which is primarily determined in accordance with the medical assessment of the situation and with the general significance of professional expertise in the law of medical negligence.

Although Lord Bridge is much closer to Lord Diplock than Lord Scarman, again he is ready to modify the standard of care although in a much more modest way. His argument is that derogation from the Bolam test is justified only when a serious risk is involved: such a risk must be disclosed no matter what. In this respect, his speech in essence reverses the view taken by Lord Scarman: he seems to provide a standard of care coherent with the idea of the domination of professional expertise, but allows some room for the notion of patient's autonomy through the caveat of the communication of serious risks.

Finally, Lord Templeman also takes the view that the standard of care must be modified. His proposal incorporates into the standard the obligation of the doctor in charge to explain in details the situation to the patient and, crucially, to answer any particular question that the patient may ask. For him this is very significant, because it is not always the case that a patient is willing to know all the details of a proposed operation. Once again, the requirement of coherence is justified: the principle of autonomy is enhanced, by ensuring that the doctor is to communicate with the patient, according to the particular way that the patient sees fit.

It seems to me that the conclusion that can be reached from the speeches of at least three of the law Lords is that the theoretical proposition advanced by MacCormick accurately captures the method that they use in their reasoning. Lord Scarman, Lord Bridge and Lord Templeman all justify their modification of the Bolam test by incorporating arguments of coherence and consistency. These arguments constitute the justificatory basis for formulating the standard of care in such a way as to bind the members of the judiciary that will decide similar cases –and essentially all the similar cases- in the future. It is only in this justified way that they are ready to universalise their rulings.



### 3) *Gillick v. West Norfolk & Wisbech AHA* (HL).<sup>234</sup>

The factual background of this case is well known. Mrs Gillick set in motion a judicial challenge against the legality of the advice given by the Department of Health that doctors are allowed to provide contraceptive advice and treatment to girls under the age of 16 without parental consent. Although she won her case at first instance and at the Court of Appeal, she lost by a majority decision at the House of Lords. There, it was held that doctors are legally entitled to provide advice and treatment, if they are satisfied that the minor is mature enough to have "sufficient understanding and intelligence to enable him or her to understand fully what is proposed".<sup>235</sup> This decision opened up the possibility of minors being able to consent to treatment without previous parental consent and significantly changed the position held until then.

What I intend to do here is to discuss the reasoning of the majority of the House of Lords, in accordance with the theory of legal reasoning advanced by Ronald Dworkin.<sup>236</sup> I believe that this is a justified choice because it seems to me that his assertions regarding the nature of legal reasoning capture in a very accurate way the basis on which the case was ultimately decided. I will first present a short summary of the theory of Dworkin and then I will examine how it can be applied in the reasoning of the case.

Dworkin's theory of legal reasoning is an integral part of his general political theory, which is to a very significant extent inspired by liberal aspirations and by the primary importance of rights.<sup>237</sup> For Dworkin the understanding of what legal reasoning must be is inherently connected with the understanding of the function of the judiciary and this in turn becomes meaningful only within a political theory that advocates a particular central point for the law. This point is to ensure that "force is not to be used or withheld, no matter how useful that would be to ends in view, no matter how beneficial or noble these ends, except as licensed or required by individuals rights and responsibilities flowing from past political decisions about when collective force is justified".<sup>238</sup> In accordance with this concise formulation, Dworkin has developed a

<sup>234</sup> *Gillick v. West Norfolk and Wisbech Area Health Authority* [1986] AC 112, [1985] 3 All ER 402, [1985] 3 WLR 830, [1986] 1 FLR 224, [1986] Crim LR 113, 129 Sol Jo 738, 2 BMLR 11, [1985] LS Gaz R 3551, [1985] NLJ Rep 1055, HL.

<sup>235</sup> [1985] 3 All ER 402, at p. 423 by Lord Scarman.

<sup>236</sup> The most complete presentation of the theory can be found in R. Dworkin, 1986 and in his earlier *Taking Rights Seriously* (2<sup>nd</sup> edition, London: Duckworth, 1978).

<sup>237</sup> For a presentation of his political theory, see R. Dworkin, *A Matter of Principle* (Oxford: Clarendon Press, 1985).

<sup>238</sup> See R. Dworkin, 1986, p. 93.

complete theory about the law, the judicial branch and the process of legal reasoning that is primarily determined by the idea that law is a social practice, every instance of which has to be oriented to the fulfilment of its particular point.

As far as legal reasoning is concerned, the idea that law is a practice with a particular political function has far reaching consequences. For Dworkin, any participant in the practice of law, for instance any legal official whenever he acts under this capacity, is to contribute in the successful maintenance of law's main point. This is always the case when a judge adjudicates a dispute: the very process of adjudication is part of law as practice and therefore the procedure in terms of which the judge adjudicates is essentially linked with the essence of the law. From this starting point, it follows that a number of constraints are always present in adjudication and naturally in the method of legal reasoning that a judge employs when deciding cases. The most important of these constraints is that the judge must always take an interpretative stance towards the law: she must take into account the past record of the law as included in previous decisions and, most importantly, she must constructively interpret this record<sup>239</sup> so that she can unearth the most appropriate norm to be applied in the case at hand. It is for this reason that Dworkin claims that the category of a clear case is non-existing and that in all cases, interpretation of the law is necessary. Dworkin further elaborates on this idea by providing two particular requirements that must be met when a judge constructs a legal solution. The first is the requirement of fit: the proposed solution must be compatible with solutions already present in the past record of the law in similar cases. The second requirement is depicted under the term "justification". This notion complements the requirement of fit in the following sense: it is quite possible that a variety of solutions may fit with the past record of the law. From the matrix of these solutions, the judge has to choose the one that appears as the most justifiable, namely the one that if accepted and ultimately added to the body of the practice of law would contribute in the fulfilment of the point of the law. Within these lines, the solution that best serves the point of the law is the absolutely right one for the case at hand; accordingly, there is always scope for hoping that such a right solution is achievable. Dworkin accepts that this is just an ideal, yet he insists that this ideal correctly captures the nature of law, what he calls "law as integrity".<sup>240</sup> In order to provide a working device for the achievement of this ideal, Dworkin proposes a distinction between arguments from policy and arguments from principle. The former justify decisions by advancing some collective goal of the

<sup>239</sup> For the notion of "constructive interpretation" see in details R. Dworkin, 1986, pp. 52ff.

<sup>240</sup> For further analysis of this notion, see R. Dworkin, 1986, chapters 6&7.

community as a whole, while the latter justify decisions by securing some individual or group rights.<sup>241</sup> For Dworkin only arguments from principle can yield justifiable decisions within the context of judicial reasoning and, therefore, only that type of arguments should be used.

Going back to the decision in *Gillick*, a Dworkinian reading of the case would insist that the majority opinion at the House of Lords has generated a justified solution on the basis of an argument from principle. To begin with, the court refused to perceive the issue as a settled one and instead it took an interpretative stance towards the relevant record of the law. This stance materialised in the particular decision that took on board a principle widely accepted in the relevant field of the law. Unsurprisingly, this is the principle of autonomy that is inherently linked with the right of individuals to self-determination. In the particular context of the case, autonomy takes the particular form of reproductive autonomy: here it is expressed as the right of the individual to organise according to her own wishes her sexual activities. The fact that the individual at stake is under the age of 16 is as such irrelevant: what is crucial is the formulation of a norm according to which the right of self-determination of a mature individual is as such protected by the judiciary. The only thing that has to be addressed are the conditions in terms of which an individual is deemed to be considered mature enough, and the court actually provides a list of these conditions.

Within these lines, the decision of the court both fits with the past record of the law, in the sense that autonomy is part of the existing normative edifice and is in tune with the requirement of justification, in the sense that it originates from an argument of principle that expressly protects the rights of individuals. Furthermore, the court in deciding in such a way implicitly rejects a number of arguments from policy that could have been used, namely the need to control the sexual activities of minors and the importance of insisting on parental consent.<sup>242</sup> These being the case, the decision is compatible with a vision of law as integrity.

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<sup>241</sup> See, in details, R. Dworkin, 1978, pp. 82ff.

<sup>242</sup> For possibility of such arguments, see J. Montgomery, 2003, pp. 397.

#### 4) *McFarlane and Another v. Tayside Health Board*.<sup>243</sup>

I have already referred to this Scottish case in a previous section of this chapter. Let me start by a brief presentation of its factual background: the pursuers decided that they did not want any more children (given that they already had four), and that, accordingly, the husband should undergo a vasectomy.<sup>244</sup> A surgeon employed by the Health Board performed the operation. After having analysed a sperm sample, he informed Mr. McFarlane that the operation was successful and that other contraceptive measures were no longer necessary. However, 2 years later Mrs. McFarlane became pregnant, and after a normal pregnancy and labour gave birth to a healthy child. The couple argued that they have suffered loss as a result of negligence on behalf of the Board and claimed damages for the physical discomfort suffered by Mrs. McFarlane from her pregnancy, confinement and delivery *and* for the financial costs of caring for and bringing up the child.

What I am interested in here is to discuss the second claim of the parents, namely the one that refers to the recovery of the financial cost of bringing up the child that was born. Once again, I will do that taking on board a particular understanding of legal reasoning, namely John Finnis' analysis of legal reasoning<sup>245</sup> in the light of his natural law theory. Before doing that, I must admit that the theorising of natural law is not usually considered when the domain of legal reasoning is discussed. The analysis of why this is so escapes my present purposes.<sup>246</sup> However, it seems to me that especially in the field of medical law, an analysis of legal reasoning that considers some insights from natural law theory may yield interesting and often neglected results. This is why this section is included. In order to clarify my point, I will first revisit the decisions reached at each judicial stage and then I will advance the theoretical analysis.

In the Outer House, Lord Gill dismissed the claim on the basis that the process of normal pregnancy and labour cannot constitute personal injury even when undesired. In addition, he argued that the benefits of parenthood transcend any financial loss that is incurred as a result of the child's existence. It follows that the parents are not in an overall position of loss and therefore they cannot recover damages.

<sup>243</sup> *McFarlane v. Tayside Health Board* 1997 SLT 211, OH; revsd 1998 SC 389, 1998 SLT 307, 1998 SCLR 126, 44 BMLR 140, CS; [2000] 2 AC 59, [1999] 4 All ER 961, [1999] 3 WLR 1301, [2000] 1 FCR 102, 52 BMLR 1, 2000 SCT 154, 2000 SC 1, HL.

<sup>244</sup> This is a surgical operation that consists of the removal of the ducts through which semen passes from the testicles. It is usually performed as a method of birth control.

<sup>245</sup> As this is mainly included in J. Finnis, "Natural Law and Legal Reasoning" in R.P. George (ed.), *Natural Law Theory: Contemporary Essays* (Oxford: Clarendon Press, 2002), pp. 134-157.

<sup>246</sup> For an introduction to this issue, see M.C. Murphy, "Natural Law Jurisprudence" (2003) 9 *Legal Theory* 241.

The Inner House reversed this decision by insisting that the main question in the case refers to the possible manifestation of *damnum* (ie a loss in the sense of material prejudice) to an interest recognised by law. Such an interest is present here, since Scots law recognises the pursuers' interest in avoiding pregnancy. This interest had been injured and therefore the relevant damage was recoverable. Within such an argument the idea that the birth of child is always a blessing was thought to be unwarranted: in any case, it was deemed that this was a matter of public policy and as such it should not influence the decision of the court that had to apply only legal norms.

However, the House of Lords unanimously discarded the decision of the Court of Session and held that the cost of bringing up the child is not recoverable. Five Law Lords delivered speeches and all of them reached the same conclusion, although on the basis of different premises. Lord Slynn of Hadley, Lord Steyn and Lord Hope of Craighead all argued that the claim of the parents was essentially a claim for pure economic loss and for this to be compensated it had to be shown that it would be fair, just and reasonable to impose liability, a requirement that was not satisfied in the particular case. Lord Steyn further argued that considerations of distributive justice do not permit the parents of a healthy but unwanted child to claim as compensation the cost of its upbringing. Lord Clyde insisted that a compensatory relief of the financial obligations of the parents related to the care of the child would go beyond the scope of a reasonable restitution of the harm done to them. Finally, Lord Millett regarded the birth of a child as a blessing and argued that the advantages and disadvantages of parenthood are intrinsically linked together in such a way that the benefits outweigh any loss, with the collateral result that no compensation should be awarded.

It seems to me that what brings all these different opinions together, is a certain unease to award compensation for the birth of a healthy child. The source of the unease is the importance attached to life in all its manifestations, which obviously includes birth. This importance is probably more accurately captured by the idea of the sanctity of life, the most significant aspect of which is the essentially incommensurable nature of life, in terms of which the value of human life cannot be measured in accordance to any metric system.<sup>247</sup> Accordingly, the complicated nature of the case is triggered exactly by the parental claim to be compensated for a birth, since this claim essentially transforms the incommensurability of life into something commensurable. This is the source of the judicial unease; this also applies to the decision of the Court of Session that discards this

<sup>247</sup> For an introduction to the notion of incommensurability, see C.R. Sunstein, "Incommensurability and Valuation in Law" (1994) 92 *Michigan Law Review* 779.



irritation by insisting on a formal solution while simultaneously acknowledging that an issue of public policy is present here, but as such it is beyond its authority. In all the other opinions this unease is quite explicit and this is probably the main reason for the generation of differently argued solutions: the judges attempt to couch the problem of life's incommensurability in different legal principles, with the common aim of rejecting the claim.

Finnis' theory captures this problem in very explicit terms. For Finnis, human life is a basic good<sup>248</sup> and as such a basic reason for action, in the sense that all action has to be oriented to its better fulfilment.<sup>249</sup> As with all the other basic goods, human life is an incommensurable good and is very much linked with the domain of moral choice. In essence, it is in this domain that it primarily constitutes a reason for action, by providing guidance for moral choices. Being a basic good it can only offer open-ended guidance and therefore it allows for many different options regarding its exact fulfilment. On the contrary, legal reasoning belongs to a different realm of reality: it belongs to the domain of technique and has a very particular function, namely to achieve a settled resolution of disputes.<sup>250</sup> For Finnis, legal reasoning is not immune from participating in the resolution of moral choices; on the contrary, there exist inherent moral values in law and these are present in adjudication. However, as the law belongs to a different order of reality there is no guarantee that it will be able to contribute to the moral choice in a satisfactory way. When this is the case and, more importantly, when an open-ended moral problem is expressed in legal terms, the law may be unable to provide a solution on its own terms and the moral problem reappears as such.

In the case I am discussing, it can be argued that this is exactly what is happening. The courts involved are called to opine on an essentially moral issue, namely on how the basic good of human life would be better fulfilled under the particular circumstances. By definition, human life is incommensurable, yet the dilemma that is present here allows for the opposite possibility, namely to consider life as commensurable for the purposes of this claim. Since the law is unable to solve this dilemma, it reappears as a moral question and it is solved by each individual judge according to his own moral feeling. Quite unsurprisingly, as soon as the moral dilemma is solved, the solution is redrafted in legal terms and ultimately appears as the legal solution.

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<sup>248</sup> See J. Finnis, *Natural Law and Natural Rights* (Oxford: Clarendon Press, 1980), pp. 84-85.

<sup>249</sup> See J. Finnis, 2002, p. 135.

<sup>250</sup> See J. Finnis, 2002, pp. 141-142.

5) *R v. Cambridge District Health Authority, ex p B (CA)*.<sup>251</sup>

B, a 10-year-old child, had been suffering from lymphoma from the age of five. After a lengthy course of different treatments, the doctors in charge of his care reached the conclusion that there was no point in administering further treatment and predicted a very limited life expectancy. B's father obtained a different medical opinion from the USA, according to which further treatment would carry an 18% chance of full recovery. Doctors in the UK insisted that the chance of recovery was much lower; also, it subsequently emerged that due to scarcity of hospital resources, the proposed treatment would have to be carried out privately, with an estimated cost of 75,000 pounds. The health authority in charge of the care of B refused to provide the funding, arguing that not only would the proposed treatment not be in B's best interests, but also that the use of a significant amount of money for a treatment with such a low chance of success was essentially an ineffective use of the limited resources at its disposal. The father of B sought judicial review of this decision. In the High Court, Laws J decided in favour of the father and ordered the authority to reconsider its decision. The authority appealed.<sup>252</sup>

The Court of Appeal overruled the decision of the High Court. It insisted that it was only the lawfulness of the refusal of the health authority to provide funding that was to be adjudicated and that it was not within the judicial function to provide judgement regarding the (contested) medical merits of the proposed treatment. Additionally, and even though the health authority also argued that what was proposed was not in B's best interests, it was the argument regarding the allocation of resources (in this case the 75,000 pounds needed) that was of crucial significance. In essence, the court held that it was indeed *within the power of the health authority to decide how its limited resources would be more efficiently used*, on the condition only that the parents of B had been properly consulted. As this condition was met, the authority was entitled to reach the decision that it actually reached especially given the fact that limited resources is part of the reality of health care provision. Interestingly, Sir Thomas Bingham MR explicitly accepted the importance of limited resources:

"I have no doubt that in a perfect world any treatment which a patient... sought would be provided if the doctors were willing to give it, no matter how much it costs... It

<sup>251</sup> *R v. Cambridge District Health Authority, ex p B* [1995] 1 FLR 1055, [1995] Fam Law 480, 23 BMLR 1, [1995] 2 All ER 129, [1995] 1 WLR 898, CA.

<sup>252</sup> For a very detailed account of all the issues regarding this case, see C. Ham and S. Pickard, *Tragic Choices in Health Care: The Case of Child B* (London: Kings Fund, 1998). It is also interesting to refer to V. Entwistle *et al.*, "Media Coverage of the Child B Case" (1996) 312 *British Medical Journal* 1587, regarding the involvement of the general public with the case.

would, however, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world."<sup>253</sup>

Based on this reasoning and with further help from the argument that the proposed treatment was at best a marginal treatment, it comes as no surprise that the Court of Appeal opined in favour of the health authority.<sup>254</sup>

This case was decided on the basis of the particular constraints of the process of judicial review, which insist on the procedural legality of the challenged decision.<sup>255</sup> Nonetheless, it is not necessarily helpful to admit that this was the main reason for focusing so much on the problem of limited resources, at the expense of the clinical aspect of the situation. In my view, it is more meaningful to treat this case as a telling example of what happens when the judiciary is called to opine with reference to an essentially *economic* decision. Although the father, in contesting the withholding of funding, is naturally motivated by the well being of his child, what he does is to complain against a decision regarding clinical priorities that takes place in a real environment of limited resources. In this respect, the explicit counter-argument of the health authority that this particular funding would be an inefficient use of resources<sup>256</sup> is not only sound, but very informative as to the exact nature of the dispute: this is essentially an economic dispute, regarding the proper management of funds. Accordingly, the court gets involved in order to scrutinise an economic decision and its ruling has a clear economic impact. This being the case, it seems to me that an "economic" reading of the case is very helpful in revealing its most significant features.

The economic rationale and the economic impact of judicial decisions has been thoroughly analysed by a school of thought usually depicted under the rubric "economic analysis of law".<sup>257</sup> Building on several insights from economic theory,<sup>258</sup> which are combined with the premises of utilitarianism, scholars like Richard Posner<sup>259</sup> argue that an understanding of law as a means for achieving the *maximisation of wealth* is very helpful,

<sup>253</sup> [1995] 2 All ER 129, at paragraph 16.80.

<sup>254</sup> Ultimately, the treatment was funded from both the public and the private sector, but it was unsuccessful; the child died 14 months after.

<sup>255</sup> For the possible grounds on which an application for judicial review may be granted in the context of medicine, see J. Montgomery, 2003, p. 68, with further references.

<sup>256</sup> I am not implying here that the notion of efficiency within the provision of health is free from ambiguity. On the contrary, its content is quite contested and several different ideas of what should be understood as efficient can be sustained. For further analysis of this issue, see R. Baggott, 2004, pp. 57-64.

<sup>257</sup> For a detailed presentation of the most significant insights of this approach, which remains quite popular, see A. Leff, "Economic Analysis of Law: Some Realism About Nominalism" (1974) 60 *Virginia Law Review* 451.

<sup>258</sup> Especially from the work of Ronald Coase; see his *The Firm, the Market and the Law* (Chicago: University of Chicago Press, 1988).

<sup>259</sup> See especially his *Economic Analysis of Law* (5<sup>th</sup> edition, New York: Aspen, 1998) and *The Economics of Justice* (Cambridge, Massachusetts: Harvard University Press, 1983).

both in explaining what the courts do when adjudicating, and in providing a theory of justice, in terms of which one can reach normative conclusions regarding what the judges and other officials should do. Within this theoretical framework, judicial rulings are to be understood as judicial attempts to maximise economic welfare.<sup>260</sup> This applies notwithstanding the language that is engaged in the rulings; indeed, it is rarely the case that the courts refer explicitly to economic criteria. However, the inherent rationality of the applicable legal norms and the mode of their judicial interpretation, both ensure that in essence, all common law can be explained in the light of economics.

Going back to the case at hand, it seems that implicitly but decisively, the Court of Appeal adopts a stance that makes sense primarily in economic terms. Even though at first glance the court abstains from substantively evaluating the decision of the health authority, this very abstinence can be explained in economic terms. In essence, what the court maintains is that from an economic point of view, the body more able to reach a correct decision regarding the efficient allocation of limited resources is the body that is actually in charge of these resources, namely the health authority. In economic terms, a substantial intervention of the court would probably generate an inefficient solution; hence the decision of the authority was sanctioned. This stance is compatible with a liberal, non-interventionist ideal that insists that the best way for achieving efficiency is to allow the relevant sector of society to reach the proper solution on its own. Given that the judiciary belongs to the wider apparatus of the state, it comes as no surprise that non-intervention is deemed as the correct legal *and* economic solution.

Is this reading of the case plausible? This of course can be contested, but in my view the economic analysis of law provides a useful platform for explaining the insistence on the allocation of resources and the non-interventionist outcome. Also, it helps to explain why the question of the best interests of B was, here, intrinsically linked with the pragmatism of limited resources. The management of scarce resources falls properly within the domain of economics; thus, an economic reading of the case shows that the substantiation of the best interests principle is not determined by clinical and quality of life considerations alone, but that it ultimately relates to the broader issue of economic efficiency in health care provision.

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<sup>260</sup> See R. Posner, 1983, p. 4

## E. Conclusion.

The aim of this admittedly long chapter was to present the normative content of the law's involvement with medicine, as this has actually taken place so far. Having reached the end, and with the reminder that this was only a partial presentation that left many issues in the dark, it seems to me that at least one very significant conclusion can be reached, namely that the field is characterised by a degree of *internal complexity* that should not remain unnoticed.

I use the term complexity here as a shorthand that indicates several significant issues. Let me present them in the form of five statements that capture quite accurately what I mean by claiming that there exists complexity in the field:

- a) The law interferes with medicine either through adjudication or through legislation; however, it is not clear whether a pattern can be identified, able to explain why the one form of regulation is actualised at the expense of the other. It appears that an element of randomness is present, especially in terms of the technical aspect of medicine. This randomness is further intensified by the sheer quantity of the relevant material. In any case though, there is no doubt that adjudication is of crucial importance for the actuality of the discipline and that more often than not the *courts* are called upon to opine about new developments in medicine.
- b) In the justification and interpretation of the relevant norms, there seems to be a constant (although implicit) presence of all the "shareholders" in the domain of medicine. The interests of health professionals, scientists, patients, the state etc. are all mirrored through the use of concepts that arguably emanate from those interests, but are couched in legal terms. The notion of autonomy or the delineation of the best interests test according to the medical view, are just the most obvious examples. In any case, the exploration of the field simply highlights that these different interests are present; the balance between them is constantly unstable and the tension between conflicting or simply different stakes is rarely resolved in a definite manner.
- c) This last point is very much exemplified if one considers the organisation of the provision of health care. Here, a variety of different interests conflict with each other: for instance, the gradual openness of the NHS to market forces (through the welcoming of the involvement of the private sector) contradicts a trend against commercialisation that is present in other areas, like transplantation of organs and reproduction. Similarly, the regulatory framework of the health care professions and of the NHS is fraught with



mechanisms of control of the conduct of health care professionals. Against this trend, one cannot but notice that the judicial handling of the same individuals is characterised by a very significant degree of respect to professional authority and autonomy.

d) In combining the above statements, it becomes obvious that medical law is sensitive to a wide variety of influences. In this respect, it develops in a very *particularistic* manner: both judicial decision-making and parliamentary intervention are oriented to the particular nature of the case or the area that they refer to and they integrate different factors according to this particularity. As a result medical law is generally characterised by a dense *substantive* rationality.

e) Finally, even in the field of legal reasoning, the plateau where coherence is often depicted as a desirable ideal, randomness is also present. Different considerations and, quite often, different modes of reasoning are employed – my enquiry shows that formal, ethical, economical and probably political considerations all shape the *way* according to which the courts decide medical cases. This further means that even if some of the modes of reasoning are consistent with theories that underlie the importance of coherence, it is the notion of *incoherence* that best captures what is happening in the field.

These findings must be combined with the conclusion of the previous chapter, namely that the doctrinal analysis has not been so far able to provide a plausible argument regarding the subject matter of a supposedly coherent discipline of “medical law”. Is this not another indication of a significant degree of complexity? For me the answer is affirmative and additionally, it indicates exactly how I use the term complexity in this chapter. In effect, I take complexity to signify a lack of internal coherence, in the sense that the field cannot be described according to a unified set of principles in terms of which settled conclusions can be reached. On the contrary, my point is that the orientation of law towards medicine has produced an internal normative horizon where conflicting principles are present in abundance and where inconsistency is the norm rather than the exception: within the field of medical law a point of equilibrium is not easy to find. This is exactly what the term internal complexity depicts at this stage of my thesis.

This being said, the need to explain why such a complexity is present seems to me a task worth pursuing. Clearly, one could tackle the issue from many different perspectives and with different foci of inquiry. For instance, it is arguable that the balance between legislation and adjudication can be explained from the point of view of a political analysis that may identify the reasons why the state decides to intervene in

certain areas directly and not in others; equally, the size of the relevant case law can be analysed from a perspective emphasising the reasons that underlie the phenomenon of litigation. Similarly, a sociological analysis could explain the simultaneous presence of different interests as a marker of how the struggle between these interests is evolving in society; even my own discussion regarding medicine as a professional jurisdiction implies as much. Finally, the complexity of the legal reasoning could be explained by any theory that would be ready to argue that the process of reasoning is essentially open to general societal pressures that may take different forms.

I have no doubt that all these approaches can provide crucial insights regarding the problem of complexity that I have identified. However, all of them are helpful in explaining complexity only if one is willing to *externalise* it, namely to treat it as an indication of phenomena that take place outside the law. This shifts the emphasis away from an *internal* perspective that would treat complexity as a phenomenon that resides *within* the law. Such a perspective is crucial in a very significant respect, namely in that it shows that complexity indicates something about the nature of medical law *itself*. By advocating an internal point of view, the focus returns to the law and the question that has to be answered is the following: what does the existence of internal complexity reveal regarding the very nature of law's orientation to medicine?

It is my firm belief that this kind of questioning is the most fruitful for furthering our understanding of how medical law is constituted. This is why I consider that a discussion of complexity from an internal perspective is apposite to the initial question of my project. This is exactly what I will do in the next chapter, where I will turn to a more theoretical analysis. In essence, what I will do there is to provide a theory that takes on board internal complexity and to explore what such a theory unearths regarding the emergence of new disciplines in the process of legal regulation. In the light of this proposed theoretical framework, I will provide a concrete platform for tackling the initial question of my thesis. This platform will be then applied to medical law in the fourth and final chapter of the thesis.

## **Chapter 3**

### **Legal Regulation**

#### **From a Systems-Theoretical Perspective**

## A. Introduction.

In the previous chapters of the thesis, I undertook an unpacking of the discipline of medical law as it stands, on the basis of which two conclusions were reached. The first conclusion is that the doctrinal propositions on the subject matter of medical law are implausible and thus that they cannot sustain the constitution of medical law as a distinct discipline. The second conclusion is that the empirical material of medical law is characterised by a significant degree of complexity, that can be understood –at least ostensibly– as a high “concentration” of substantive instead of formal rationality within this branch of the law.

Let me now introduce this chapter, by highlighting the importance of an additional remark that in a sense brings these two conclusions together, although in an oppositional manner. On the one hand, the doctrine insists that it is possible to define coherently what medical law is. The fact that the relevant propositions that have so far been advanced are implausible, does not mean that the goal itself is unachievable: maybe we simply miss an adequate conceptualisation, which will eventually describe accurately the subject matter of medical law and organise the discipline accordingly. On the other hand, though, the complexity identified in chapter 2 is so significant and so multi-layered that maybe a doctrinal constitution of medical law is beyond the doctrine’s range. Indeed, it may signify that any doctrinal attempt to gather this empirical “variety” as a coherent body under adequate concepts has no chance of success.

In effect, a discrepancy exists here, which has not been seriously considered so far and which, although under-theorised, is very important for any attempt to assess how the discipline of medical law can be constructed. Therefore, in the chapter at hand, *which aims at presenting a theoretical argument on the basis of which the constitution of medical law will be reassessed*, I will take on board this discrepancy as the starting point for the choice of the theoretical perspective adopted here. This means that I will be based on a theory that integrates the significance both of complexity and of the founding presuppositions of the doctrinal definitions, namely that medical law becomes constituted in the process of the regulatory orientation of law towards medicine.

This latter remark determines the exact structure of the chapter. In the next two parts, I will explain in detail the main tenets of the theoretical view that best fits my purpose. Then, I will analyse the problem of regulation and in the light of the same theory, I will explain exactly how the intensification of legal regulation determines the

constitution of new, autonomous disciplines within the law. In the final part, I will summarise my findings in such a way as to apply them directly to the constitution of medical law. This task will be the subject matter of the next chapter of the thesis.

## B. Complexity as an object of theoretical enquiry.

I will begin my discussion by following closely some insights from the doctrinal propositions. At this level, the argument in effect is that the subject matter of medical law (the identification of which determines how the discipline is constituted) must be defined in terms of the crystallisation of law's response to an external theme originating from medicine – whatever this theme may be. This assertion presumes that the law is called upon to deal with a specific problem or a cluster of problems, which for some reasons require regulatory intervention. In turn, this is based on the idea that the law is an instrument that can be used for political reform, or more generally a mechanism that can steer social action; that is why it is assumed that specific changes in various social spheres (in our case medicine) can be achieved through law. At a further level of generalisation, the acknowledgement of the possibility of social guidance through law is based on the fundamental belief that the law can both integrate issues originating from the non-legal world and also penetrate this world through regulation. To put it in a more sophisticated language, the doctrinal propositions are ultimately connected with the idea that the law is an *open system*, which receives questions from other societal spheres as input and generates relevant regulatory solutions as output.<sup>1</sup>

From a sociological point of view, any perspective based on the notion of open systems treats social institutions and organisations as autonomous units that constantly interrelate directly with their environment.<sup>2</sup> It highlights issues like adaptation, maintenance, variety and equilibrium. Especially as far as regulation is concerned, an open systems perspective would stress the possibility of rational organisation of means towards particular ends and would theoretically support the possibility of direct social

<sup>1</sup> For a detailed analysis of the argument that the law is an open system, see L. Friedman, *The Legal System: a Social Science Perspective* (New York: Simon & Schuster, 1975), pp. 5ff.

<sup>2</sup> This theory has its origins in biology. For the original idea, see L. von Bertalanffy, "The Theory of Open Systems in Physics and Biology" (1950) 111 *Science* 23, whereas for its application to sociology see, amongst many others, W. Buckley, *Sociology and Modern Systems Theory* (New Jersey: Prentice Hall, 1967) and D. Katz and R.L. Kahn, *The Social Psychology of Organizations* (New York: Wiley, 1966).



intervention, through a wide range of mechanisms.<sup>3</sup> In brief, this perspective establishes the regulatory potential of the law as a relational issue, which is determined by the actual interaction between the legal system and its environment in accordance to an input-output model. The presupposition that medical law is constituted as a discipline because the law reacts to problems emanating from medicine and that these problems can be regulated through law is the self-evident consequence of the implicit affirmation of an open-systems perspective; it is also the cornerstone that sustains the whole doctrinal edifice of medical law as it now stands and is embedded in the practical view point that the doctrine adopts.

Nevertheless, the effect of actual attempts for social change through law cast a shadow on the uncontested plausibility of the open systems approach. Although regulatory efforts certainly have a significant impact, it has gradually been noticed that this is not always the expected one. Often, the regulated areas show a contingent degree of sensitivity to regulatory projects: sometimes, regulatory projects fail for no obvious reasons, whereas on other occasions they achieve results beyond the pre-existing expectations in a rather paradoxical manner.<sup>4</sup> In addition, even the idea of a rational organisation of legal structures towards particular ends seems itself to collapse: legal regulation is often shaped in a contingent way, through isolated legislative initiatives and complicated judicial decisions, as the example of the internal complexity of medical law perfectly highlights. The conclusion that can be reached is that the mobilisation of the law as a means for achieving particular aims may result in unpredictable outcomes, which are expressed as an increase of the complexity both of the legal system and of the regulated field. This unpredictability is not very welcome from a theoretical point of view: according to the paradigm of open systems a direct, rational and efficient intervention through law is achievable and, therefore, because of this detected unpredictability something must be missing. Naturally, efforts have been made, from within the open systems model, to understand the contingency of legal regulation up to this point and to provide solutions.<sup>5</sup> However, the problem seems to persist. Ultimately, this realisation has necessitated a different theoretical paradigm,<sup>6</sup> able to integrate

<sup>3</sup> For further analysis, see G. Teubner, *Law as an Autopoietic System* (Oxford: Blackwell, 1993), pp. 13-14.

<sup>4</sup> For this point, see in details G. Teubner, "After Legal Instrumentalism: Strategic Models of Post Regulatory Law" in G. Teubner (ed.), *Dilemmas of Law in the Welfare State* (Berlin: de Gruyter, 1985) and 1993, pp. 13-15.

<sup>5</sup> For an introduction, see R. Cotterrell, *The Sociology of Law: an Introduction* (2<sup>nd</sup> edition, Edinburgh: Butterworths, 1992), pp. 50-53 and 59-63.

<sup>6</sup> For the history of the realisation of the need to change paradigm, see G. Teubner, "Evolution of Autopoietic Law" in G. Teubner (ed.), *Autopoietic Law: A New Approach to Law and Society* (Berlin: de Gruyter, 1988), pp. 217-241, at pp. 218-220.

empirical unpredictability and complexity. This paradigm has been found in a new version of *systems theory*,<sup>7</sup> primarily developed in the work of Niklas Luhmann.<sup>8</sup>

Luhmann starts from the premise that the social universe is strikingly *complex*, characterised by an infinite number of possibilities, discontinuities and alternative options. Against this background of complexity, the most fundamental sociological task is to explain how social interaction and ultimately society is possible. Indeed, this appears as an *improbability* given that intense complexity generates *contingency* that runs through the whole social world and hinders the possibility of building up constancy of patterns of social interdependence.<sup>9</sup> This formulation of the issue invites the theory to come up with a way of solving the familiar problem of “double contingency”,<sup>10</sup> according to which the very possibility of social interaction is dependent upon the stabilisation of a particular interactional context. This means that the meaningful unfolding of any social interaction, the exact content of which is by definition contingent (first-order contingency), can only happen within a context, the particular settling of which is also contingent (second-order contingency). To provide an example: one can choose to agree or disagree with someone else (first-order contingency); however, it is indispensable to know *about what* (second-order contingency) one agrees or disagrees, otherwise nothing would make sense. Consequently, the necessary presupposition of any interaction and more generally of society itself as a meaningful, ordered “entity” is the possibility of stabilising contexts of interaction.

Luhmann solves the problem of double contingency, by proposing a radical departure from traditional sociology: he claims that instead of taking action as the elementary unit of the social, the focus should be on *communication*.<sup>11</sup> Society represents

<sup>7</sup> This theory takes shape accommodating a variety of influences and most notably: (obviously) general systems theory (see L. von Bertalanffy, 1950)); biological ideas regarding the autopoietic character of living organisms (see H.R. Maturana and F.J. Varela, *Autopoiesis and Cognition* (Boston: Reidel, 1980) and F.J. Varela, *Principles of Biological Autonomy* (New York: Elsevier, 1979)); cybernetic models regarding the possibility of systemic interaction (see H. von Forster, *Observing Systems* (Seaside, California: Intersystems Publications, 1981)); mathematical models of logic (see G. Spencer-Brown, *Laws of Form* (New York: Julian, 1972)); sociological understandings of the notion of self-reference (for the debate regarding this notion, see G. Teubner, 1993, p. 15, with further references)); finally, the theoretical premises of functional differentiation (see, in details, T. Parsons, *The Social System* (London: Routledge & Keagan Paul Ltd, 1951) and T. Parsons and E.A. Shils (eds.), *Toward a General Theory of Action: Theoretical Foundations for the Social Sciences* (Harvard: Harvard University Press, 1951)).

<sup>8</sup> The most detailed presentation of the theory can be found in N. Luhmann, *Social Systems* (Stanford: Stanford University Press, 1995a).

<sup>9</sup> See N. Luhmann, 1995a, pp. 114-117.

<sup>10</sup> Originally formulated by Talcott Parsons and classically summarised in 1951, p. 105.

<sup>11</sup> Although this is a founding argument of all Luhmann's work, its most explicit exposition can be found in N. Luhmann, “The Concept of Society” (1992) 31 *Thesis Eleven* 67 and in 1995a, pp. 137ff. Not surprisingly, this thesis has been the focus of intense criticism, especially for the collateral “subordination” of action to communication; for an introduction to the relevant debate, see E. Christodoulidis, *Law and Reflexive Politics* (Dordrecht: Kluwer Academic Publishers, 1998), pp. 75-76 and also G. Teubner, 1993, p. 43.

the totality of communications<sup>12</sup> and therefore complexity, at the social level, equals communicative complexity. It follows that the problem of double contingency in society must be reformulated as a problem of setting up communicative contexts. In Luhmann's terms this task should be understood as a *reduction achievement*, because the establishment of a context reduces the infinite social complexity into a "particularised" complexity, which is tolerated and processed as such by the context itself. It is important to stress that any contextual reduction provides a solution to double contingency: it eliminates second-order contingency and, thus, it allows for the meaningful unfolding of the first-order contingency. It is only within a stable, communicative context that human interaction becomes meaningful.

Within this theoretical framework, *systems* are perceived as "agents" that make the reduction achievement possible, that stabilise contexts and handle complexity.<sup>13</sup> As far as society is concerned, social systems fix communicative contexts and are themselves systems of communication.<sup>14</sup> They attain this by providing internally defined *recurrent* schemes for processing communication and therefore they manage complexity only by existing, as distinct systems, in time. The medium that social systems use in doing this is *meaning*: they stabilise communicative contexts by providing system-specific meaning-related networks of structures that endure in time.<sup>15</sup> These structures impose particular reductions to the social (communicative) universe and they orchestrate the very possibility of meaningful interaction, by particularising the abstract and undefined possibilities that exist in the social domain.<sup>16</sup> To put it in a simpler manner, what systems achieve is the stabilisation of specific types of meaning: the contexts that they fix are meaning-related contexts, only within which meaningful interaction can be attained.

Let me insist for a while on the consequences of the system-specific achievement of reduction. To begin with, it must be understood as a paradoxical achievement in the following sense: although systems reduce complexity in order to ensure meaningful communication, when doing so they simultaneously contribute to the intensification of

<sup>12</sup> See N. Luhmann, 1992, *passim*.

<sup>13</sup> For a definition of what should be understood as "system", see N. Luhmann, *Law As A Social System* (Oxford: Oxford University Press, 2004), p. 78.

<sup>14</sup> Within the infinite complexity of the world, which includes the realm of non-communications, other types of systems are also present. For example, in his typology of systems (in 1995a, pp. 2ff.), Luhmann distinguishes between living, psychic and social systems.

<sup>15</sup> It goes without saying that the possibility of communication is inherently linked with the problem of how meaning emerges. For this, see in details N. Luhmann, 2004, pp. 144-145.

<sup>16</sup> One could generalise further and argue that only through systemic reduction is meaning possible *in general*, as its very possibility is conditioned upon the setting up of a context against the loose and undefined complexity of the communicative universe.

the general communicative complexity.<sup>17</sup> This is because any emerging system-specific stabilisation of meaning generates a new communicative possibility, which registers within the societal domain and therefore increases the already existing matrix of alternative options.<sup>18</sup> This should not be seen as a contradiction, but rather as an unavoidable side effect of interacting in a complex world. As such, this double effect of systemic reductions is itself managed within systems: as general societal complexity tends to intensify, systems elaborate on their internal structures and become themselves more complex in response.<sup>19</sup>

In order to further elaborate on the reduction achievement it must be stressed that it rests completely on the possibility of an *internal* organisation of a system-specific context. Only internal operations that utterly depend on systemic elements, structures and events are mobilised as soon as a particular context is stabilised. Therefore the reduction of complexity is always system-specific and it is contingent on this "internalisation" of the complexity of the world. It follows that it is presupposed and also actualised in all the possible operations of any social system. It rests on the core of the very nature of systems and in a sense –as a *particular* reduction- it determines them. This latter point justifies the explanatory strength of ostensibly paradoxical notions like self-reference and autopoiesis, which further elaborate on how a system thus conceived is constantly referring back to itself in order to generate new operations.<sup>20</sup> Social systems must be circular, self-referential systems because otherwise they would not be able to stabilise meaningful interactions and would fail to accomplish the reduction of complexity. As a consequence, systems make sense of the world *only* on their own terms and perceive everything *only* within their own internally defined horizon of understanding. It is crucially in this respect that systems theory provides a more sophisticated account than the open systems approach, according to which systems operate using external points of reference that exist independently of systems.

This latter remark does not imply that systems do not interrelate with their environment, nor does it advocate a constructivist understanding of social reality.<sup>21</sup>

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<sup>17</sup> It must be stressed here that society as the totality of communication is itself a system contrasted with the non-communicative world.

<sup>18</sup> See, in details, E. Christodoulidis, 1998, pp. 83-84.

<sup>19</sup> I will come back to this point in the course of my discussion.

<sup>20</sup> At this point of the argument, I am referring to the rich conceptual apparatus of systems theory only with the aim to clarify my point about the reduction achievement. Concepts like operation, self-reference, autopoiesis etc. require a much more sophisticated discussion to which I will return in the next section.

<sup>21</sup> For the epistemological premises that underlie systems theory, with a particular focus on law, see G. Teubner, "How the Law Thinks: Toward a Constructivist Epistemology of Law" (1989) 23(5) *Law and Society Review* 727, especially at pp. 736ff.

However, it shifts the focus away from an input-output model and stresses that this interrelation must take into account that social systems are essentially self-referential systems.<sup>22</sup> By applying this approach to law and by arguing that the law is itself a self-referential system of communication,<sup>23</sup> the problem of regulation, and with it the problem of the constitution of medical law, appears in a different light: against the open systems approach, one needs to investigate how the law can interrelate with other systems, which are themselves self-referential and which also perceive the world internally.<sup>24</sup> Although this sounds paradoxical, it is the necessary conclusion of a theory which, building upon the notion of complexity and the need for its reduction, advocates the self-referential character of social systems. Accordingly, in the next section I will investigate in details how the law, understood as a self-referential social system, interrelates with its environment.

### C. Law as a social system.

#### 1) Basic concepts.

In what follows I will introduce some fundamental concepts of systems theory, in order to facilitate the reader's understanding of what law and legal regulation entail according to the theory. This is not supposed to be a complete exposition of the theory, nor a full account of the law as a social system. Rather, it is simply a selective summary of some crucial insights. Also, I must stress that all the concepts employed here should be understood as analytical tools that are necessary for any attempt to make sense of the world of social systems; as far as social reality is concerned, one can empirically identify only its "matter", namely communications.<sup>25</sup>

<sup>22</sup> For a detailed analysis of phenomena that are linked with self-referentiality, see G. Teubner, 1993, pp. 19ff.

<sup>23</sup> This argument may indeed have radical repercussions, not least because traditionally law is understood to contribute to the normative foundations of *action*. For this tradition, see, amongst many others T. Parsons, "The Law and Social Control" and H.C. Bredemeier, "Law as an Integrative Mechanism" both in W.M. Evan (ed.), *Law and Sociology: Exploratory Essays* (Glencoe: Free Press, 1962), pp. 56-72 (Parsons), 73-90 (Bredemeier).

<sup>24</sup> A switch from an open systems approach to a systems-theoretical approach has further consequences: it necessitates a change of emphasis from design/control to autonomy and environmental sensitivity and from regulation to systemic co-evolution. See, in details, G. Teubner, 1988, p. 217.

<sup>25</sup> For this point see N. Luhmann, 2004, p. 84 and 209.



### a) System and environment.

In the previous section, I claimed that social systems constitute planes that reduce the communicative complexity of society. In a close inspection, these systems emerge by establishing a sharp distinction between themselves and whatever remains beyond them, namely their *environment*. To put it crudely, systems introduce an artificial “point” within the unmarked, undifferentiated social reality, a point that splits the whole of reality into two sides. This point serves as the boundary between the system and its environment and as such not only distinguishes between the two sides (system/environment) but also ensures that the sum of the two constitutes the totality of reality. Importantly, this basic distinction opens up the possibility of making sense of the world, by providing a starting point for *observation*: anything can be observed as belonging to the one or the other side of the distinction. Observation is a concept that conditions all cognitive and ultimately communicative activity and it always requires a distinction: only because something is distinguished, it becomes possible to talk about it.<sup>26</sup> Only in this way can meaning emerge, because only through a system-specific basic distinction, it is possible for the cognition of an object of observation *as an object of observation* to be achieved. Of course, this opens up the possibility of plurality: as long as different points of observation appear, different systems become established and different types of meaning follow. As a result, meaning is always system-specific and always depends on the system’s particular mode of observation.

In a world consisting of a plurality of meaning-related systems, it must be stressed that all of them are established through a specific boundary, namely the particular, unique difference that they employ in distinguishing between system and environment. This claim has a twofold implication. *First*, it implies that the distinction between system and environment is controlled by the system and therefore there are as many such distinctions as there are systems. Accordingly, the environment should not be understood as an ever-present state that constantly surrounds all social systems. The notion of “environment” is relative to the emergence of a concrete system and is always

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<sup>26</sup> Although this basic distinction controls the very possibility of observing, it cannot simultaneously be used *and* be observed; as a starting point it has to be a blind spot, otherwise it could not provide the basis for a particular observation. Of course it can be observed, but only as an object and therefore only through a different distinction that establishes another kind of observation, namely a “second-order” observation. For this point, see N. Luhmann, 2004, pp. 182, 191. However, this does not mean that the system is unaware of its blind spot; on the contrary, because of the existence of *redundancy* (a concept to which I will focus later on the discussion) the system realises that it observes reality in a particular way, although it is unable to observe its mode of observation. See, in details, S.C. Smith, “The Redundancy of Reasoning” in Z. Bankowski, I. White and U. Hahn (eds.), *Informatics and the Foundations of Legal Reasoning* (Dordrecht: Kluwer Academic Publishers, 1995), pp. 191-204, at p. 198.

attached to it, since it constitutes the other side of the distinction that conditions the emergence of the system in the first place. System and environment are constructed simultaneously, they both assume each other and the difference between the two is always system-specific.<sup>27</sup> *Secondly*, the drawing of the boundary embodies the unique character of the system and it is based on the particular way that the system employs, in making sense of the world. This means that the boundary that designates the difference between system and environment is itself shaped as the outcome of a particular distinction, namely the one that the system is using in order to observe.<sup>28</sup> So, through the system-specific boundary the whole of reality is split in two sides, the one that observes according to a particular distinction (the system) and the other that does not do that (the environment).<sup>29</sup> This elementary distinction is in essence the formative precondition for the existence of any system, because it sustains its system-specific observation, it establishes its difference with its environment and it is assumed in all its operations.<sup>30</sup> Ultimately, it is the major prerequisite of the reduction achievement, because through its constant application, the system stabilises its particular meaning and fixes a communicative context.

In system-theoretical terms, this basic distinction is called a “guiding distinction”.<sup>31</sup> All kinds of systems employ such a distinction in order to become differentiated from the environment. As far as social systems are concerned and especially functionally differentiated social systems,<sup>32</sup> the guiding distinction takes the form of a *binary code*, namely a code that integrates a positive and a negative meaning-related attribution. All social systems communicate about reality by employing their binary code and by applying in any particular instance the one or the other side of its basic polarity.

<sup>27</sup> This being the case and against the open systems approach, it must be stressed that systems do not expand or reassess their boundaries within an over-compassing environment. The environment is always a system-specific environment.

<sup>28</sup> So, whenever an external observer attempts to identify a social system, what is necessary is to identify the distinction that the system is using in observing the world. This process can again be described as second-order observation; for further details, see W.T. Murphy, “Systems of Systems: Some Issues in the Relationship Between Law and Autopoiesis” (1994) 5(2) *Law and Critique* 241, p. 250. Of course, since this is a process of observation it belongs itself to a particular system, namely the system from within which this particular observation originates. For this crucial epistemological point and more generally for the complicated repercussions of a theory that establishes its epistemology on the possibility of observing systems as being observers themselves, see N. Luhmann, 1995a, pp. 478.

<sup>29</sup> That is why there exists an inherent link between system-specific observation and the distinction between system/environment. For this point, see N. Luhmann, 2004, p. 86.

<sup>30</sup> That is why all the operations of any system replicate the difference between system and environment and this is why I previously argued that the particular reduction that any system achieves is constantly present in all the operations of the system. For this point, see N. Luhmann, 2004, p. 78.

<sup>31</sup> See in details, E. Cristodoulidis, 1998, pp. 88ff.

<sup>32</sup> I will go back to the idea of functional differentiation when discussing the function of the legal system.

Let me elaborate on this so far abstract discussion, by taking the legal system as an example. The code of the legal system, namely the guiding difference that establishes its uniqueness is the distinction *legal/illegal*. This means that the law perceives everything (rather, communicates about everything) by using this distinction: for the legal system, something makes sense only as legal or illegal. Other possibilities of meaning are simply non-existing for the legal system, which, by applying this fundamental distinction, constitutes legal meaning as a particular type of meaning and manages to reduce the communicative complexity of the world in this specific way. Through its unique code, the law sharply differentiates itself from its environment (namely, whatever does not use the distinction legal/illegal – the non legal world!) and it acquires its special identity (it is the only system that observes the world using this distinction).<sup>33</sup> It is through the application of the legal code that legal communications emerge, namely communications that are intended to have legal effects and to change legal expectations.<sup>34</sup> Ultimately, its code guarantees that the law becomes a stable system, unified as such in time: as legal communications take shape through the constant usage of the legal code and as these communications are linked together, the law is no longer a spontaneous order, but rather, like any other system, a structured constellation of code application. The legal system constitutes the unfolding of the legal code in time and occurs (as a stable system) as the sum of all the instances of the application of the legal code. Legal communications are not one-off exercises. Even a particular legal communication should be perceived as taking place within the constant production of a series of communications, each of them linked with the previous one, and each anticipating the next.<sup>35</sup> In essence, the legal system operates by *constantly* observing the world, and therefore by constantly producing legal communications based on legal communications. That is why Luhmann claims that the most elementary operations of the legal system are self-reproduction (communications furnish new communications)<sup>36</sup> and observation (the attaching of legal meaning to reality).<sup>37</sup>

So, the code controls the identity and the unity of the system in time and establishes the boundary between system and environment. Does this mean that the environment is irrelevant for the system? The answer is positively negative. The

<sup>33</sup> For the link between the code and the identity of the system, see W.T. Murphy, 1994, p. 253.

<sup>34</sup> For this short "definition" of legal communications, see N. Luhmann, "The Unity of the Legal System" in G. Teubner (ed.), *Autopoietic Law: A New Approach to Law and Society* (Berlin: de Gruyter, 1988), p. 19.

<sup>35</sup> For this point, see N. Luhmann, 1988, p. 19 and E. Christodoulidis, 1998, pp. 76-77; also, although from a different theoretical perspective, G.J. Postema, "Melody and Law's Mindfulness of Time" (2004) 17 (2) *Ratio Juris* 203.

<sup>36</sup> For an analysis of the concept of self-reproduction, see G. Teubner, 1993, pp. 20-24.

<sup>37</sup> See N. Luhmann, 1988, p. 13.

environment is indispensable for the system, in a twofold way. To begin with, its existence is necessary for the existence of the system itself: only by realising that something else exists, is it possible for systems to perceive themselves as distinct entities. Thus, systems are constantly aware of the existence of the distinction between system and environment; in theoretical terms, this distinction constantly “re-enters” the system and it remains as a lingering background for all its operations.<sup>38</sup> The law needs to be aware that there exists a non-legal world. Otherwise it would be meaningless to perceive itself *as* law. This is not as paradoxical as it sounds: only through re-entry the law becomes able to observe itself as belonging to an environment<sup>39</sup> and deal with the need of not only observing the world, but also of observing itself as an observer.<sup>40</sup> It follows that whenever the law refers to itself, it has to refer to itself as something distinct from its environment and, thus, it tacitly refers also to its environment. Only this combination of internal and external reference can sustain the identity of the legal system, or generally of any system.<sup>41</sup>

At a further level, the communicative character of social systems necessitates another link between the system and its environment. Communication must be triggered and although systems control how communications are processed, they cannot themselves provide the triggers of communication.<sup>42</sup> It is the environment that provides these triggers and stimulates communicative system-specific responses. Of course, since systems are plateaus of reduction, they completely control environmental stimuli and in all their operations they constantly refer back to their internal horizon. They select what counts as relevant according to their own criteria, they classify the information value of these stimuli internally and they decide themselves whether they prefer to be indifferent. In this respect, social systems are usually understood to be *closed* systems: they rely only on their own network of operations and only through them they continue to produce new operations,<sup>43</sup> always according to their particular mode of observation, established at the level of their unique code.<sup>44</sup> However, this only means that they internally control the handling of the environment; it does not mean that the environment does not provide stimuli or that systems exist in isolation. Without the environmental stimuli,

<sup>38</sup> For the concept of re-entry see G. Spencer-Brown, 1972.

<sup>39</sup> For this point, see N. Luhmann, 2004, p. 87.

<sup>40</sup> See E. Christodoulidis, 1998, pp. 82-83 with further references.

<sup>41</sup> For this point see N. Luhmann, *Risk: a Sociological Theory* (Berlin: de Gruyter, 1991), pp. 224-225.

<sup>42</sup> In this respect, social systems must show a high degree of “irritability”. See N. Luhmann, 2004, p. 322.

<sup>43</sup> This is exactly why social systems are autopoietic systems. For this point, see N. Luhmann, 2004, p. 80.

<sup>44</sup> This point exemplifies the very close link between observation and operation. For further analysis, see N. Luhmann, “Legal Argumentation: an Analysis of its Form” (1995b) 58(3) *Modern Law Review* 285, at p. 287, note 6.



communication would not happen and communicative systems would wither away. Accordingly, environmental openness<sup>45</sup> is essential for the very existence of systems, which of course must be combined with the essentially closed nature of their coding. To summarise, systems are simultaneously closed and open systems,<sup>46</sup> distinguished from but also aware of their environment.

In the example of the law, this assertion means that the law is open to its environment, in the sense that legal communications require a certain environmental trigger. Something must happen in the non-legal world, which must be classified as a legally relevant “event” for legal communications to emerge. This can be clarified by providing a metaphor: a legal communication is nothing but the system’s way of “talking” about its environment and in this respect the law is open. Simultaneously, however, the legal system is a closed system: it defines internally what stimuli are significant, what selections are mobilised in attributing information value to external events, etc. In any case, it constantly perceives these stimuli as legally significant or not and it is only then that it processes them as legal or illegal. So, the legal system is simultaneously a closed and open system.

The elaboration of this “dual” nature of systems is probably one of the most fruitful insights of systems theory, especially as far as the relationship between system and environment is concerned. Since the understanding of this relationship is of core significance for the very concept of regulation it requires further analysis. I am going to pursue this, in the following section by exploring the mechanisms that control this duality within the legal system.

## **b) The level of programming.**

Although the binary code legal/illegal ensures the distinct identity of the legal system, its mere identification is insufficient when one attempts to understand the operative reality of the system. Indeed, legal communications occur as particular applications of the code, but how is it possible to know what counts as legal and what as illegal in a given case? The code alone does not answer and it does not even provide any guidance – furthermore, it does not have to. The code simply guarantees through its polarity that legal meaning is conceivable and, therefore, communicatively possible. As far as the code

<sup>45</sup> For further analysis of this openness, see N. Luhmann, 2004, p. 112.

<sup>46</sup> Although this is a notoriously paradoxical assertion of the discourse of autopoiesis, it must be kept in mind that it is not in itself a radical innovation of systems theory. In truth, it is quite old and originates from cybernetics. The original source is probably W.R. Ashby, *An Introduction to Cybernetics* (London: Methuen, 1956).



is concerned, it does not matter whether something is legal or illegal. What does matter is only the possibility of observing reality in these terms; the particularisation of the code is, at this level, irrelevant and as such contingent.<sup>47</sup> Accordingly, the distinction between legal and illegal is here simply a distinction between a positive and a negative value. To push this point further, one could argue that at the level of coding, this distinction is structurally tautological: the legal can always be illegal and vice versa, without this being problematic for the code and ultimately for the identity of the system. It follows that for the concrete attribution of the values legal/illegal further elaboration is necessary and further distinctions must be drawn.

The unfolding of this tautology is achieved at the level of “programming”.<sup>48</sup> At this level, the legal system provides particular criteria in terms of which the difference between legal and illegal is given content and the ascription of the two values is concretely defined. These criteria usually appear as *conditional programmes*<sup>49</sup> and they provide particular prerequisites, the fulfilment or disappointment of which generates the concrete attribution of one or the other side of the code. Conditional programmes further ensure that the legal system is open to its environment because they force it to internalise (in the form of criteria) external values in order to sustain a concrete legal/illegal attribution – it goes without saying that this internalisation is determined exclusively by the system which therefore is once again limited by its closed nature.<sup>50</sup> By using conditional programs, the legal system determines how its code is going to be applied and by doing this it performs a kind of internal self-observation.<sup>51</sup> Through self-observation the law achieves internal constancy, because it questions how its code has been applied in previous instances and approaches this past in a controlled way. To put it in more abstract terms, what happens here is the re-entry of the distinction legal/illegal in a particular previous application of the same distinction (and not on the code itself, because this would result in an irresolvable paradox), so that the legal system can keep

<sup>47</sup> The indifference of the code regarding which of its sides is going to be activated in a particular instance ensures the unity of the code, namely its ability to guarantee a constant interplay between the two values. See, in details, N. Luhmann, 2004, p. 186, where he exemplifies this by arguing that any decision in favour of one of the sides must always take into account the possibility of preferring the other side.

<sup>48</sup> For an introduction to the relevant debate, see E. Christodoulidis, 1998, pp. 91ff.

<sup>49</sup> Luhmann (in 2004, p. 196) argues that legal programmes should always be understood as conditional and not as purposive programmes; yet, this is not necessarily the case. Purposive (namely goal-oriented) programmes can also be part of the legal system.

<sup>50</sup> For a detailed analysis of this point, see N. Luhmann, 2004, pp. 192-3; for a similar point, according to which principles serve as conditional *external references* during adjudication, see S.C. Smith, 1995, pp. 198-199.

<sup>51</sup> For the concept of self-observation, see G. Teubner, 1993, p. 19.

evolving in a dynamic, but ordered manner.<sup>52</sup> This is necessary, since the exact substantiation of the balance between legality and illegality is at the outset contingent and, therefore, it must be managed.

What renders the self-observation of the law, through conditional programmes, crucial, is the existence of the legal system *in time*. As it was argued in the previous section, legal communications generate further legal communications<sup>53</sup> and in that way the system carries the application of the code forward into the future.<sup>54</sup> Therefore, it is necessary for the legal system to develop a sophisticated internal mechanism to control this temporal linkage and to stabilise both its present and its future criteria of attribution.<sup>55</sup> Otherwise, it would not be able to exist as *a unified system in time*. As legal communications constantly reappear with the passing of time, conditional programmes, which provide selections on the *proper* links between legal communications, become structures; these structures appear as *norms* and through them it becomes possible to know in advance how a particular scenario will be assessed in the future.<sup>56</sup> In this way, at any given point in time, decisions about the attribution of the values of the code are made or are about to be made *according to past decisions*. It is exactly through norms, generated at the level of programming, that the law becomes able to manage time: norms integrate the past into the present and norms project the present into the future.<sup>57</sup> Of course, these normative structures may change, but the very possibility of change is itself conditioned on particular programmes.

To summarise, through programming the legal system acquires an elaborate internal structure and starts to operate in a complex, but highly controlled manner. It develops the ability to organise its own dynamics of change and it manages to perceive itself as a complex system and to provide *self-descriptions* compatible with this complexity. Here, the term “self-description” denotes a particular mode of self-observation that fosters the identity of the system and that is embedded on the particular programs that

<sup>52</sup> This implies that for the operative survival of the system both values (legal and illegal) are equally significant and that the binary structuring of the legal code should be understood as a “nested opposition”. For further analysis of this concept, see M. Balkin, “Nested Oppositions” (1990) *Yale Law Journal* 99, pp. 1669-1705.

<sup>53</sup> They do so, because as soon as a legal communication is exhausted it becomes part of the existing matrix of the system, in terms of which new selections will be made and new communications will occur. For this point, see N. Luhmann, 2004, p. 184.

<sup>54</sup> See N. Luhmann, 2004, pp. 179-180.

<sup>55</sup> For the crucial significance of this linkage, see, in details, H.G. Deggau, “The Communicative Autonomy of the Legal System” in G. Teubner (ed.), *Autopoietic Law: A New Approach to Law and Society* (Berlin: de Gruyter, 1988), pp. 128-151, at pp. 138-139.

<sup>56</sup> This possibility is usually depicted as “technicalisation”, which refers to the likelihood of anticipating how the code is going to be applied in a concrete future case. See N. Luhmann, 2004, pp. 187-188; it is at this level that more familiar notions, like “judicial rationality” and “error” start to make sense!

<sup>57</sup> See, in details, N. Luhmann, 2004, pp. 197-198.

the system employs.<sup>58</sup> Additionally, it achieves an internal differentiation between structures, elements<sup>59</sup> and processes, it defines sharply these categories and reproduces its unity through all of them;<sup>60</sup> it establishes its own selections and it defines how the elements generate new elements;<sup>61</sup> ultimately, it is at this level that the legal system succeeds in controlling its internal, self-referential reproduction, by providing an internal rationalisation of why the coding is actually applied in a certain way and not otherwise. In other words, the constant negotiation of the balance between the unchangeable coding and the flexible programming ensures the *autopoiesis* of the legal system.

By introducing the level of programming, it becomes possible to explain the internal sophistication of the legal system and to contrast the certainty of the coding with the flexibility of legal reality.<sup>62</sup> Also, it becomes possible to discard the critical voices against the rigidity of the code, by arguing that they underestimate the significance of programming.<sup>63</sup> Nevertheless, what this concept cannot depict is the exact link between the internal refinement it signifies and the elementary distinction between system and environment. This connection requires us to shift the focus on another conceptual pair.

### c) Redundancy and variation.

Functional social systems, like law, are differentiated as unique because of the special code they use as their constitutive guiding difference.<sup>64</sup> At the level of programming, they elaborate on their internal sophistication and they provide internal controls for the application of their code. However, it is only with reference to the code that the systems generate their particular communication and they manage to make sense of their environment. As more and more social systems become differentiated, by the emergence and the employment of new guiding differences, the complexity of the world increases. From the point of view of the legal system, this means that the legal environment becomes more complex.

<sup>58</sup> For further discussion of the concept of self-description, see G. Teubner, 1993, pp. 19-20.

<sup>59</sup> For a very sophisticated analysis of what should be understood as the "element" of the legal system, see H.G. Deggau, 1988, pp. 131ff. and G. Teubner, 1993, p. 31; more generally, for the components of the legal system, see G. Teubner, 1988, p. 222 and 1993, p. 9.

<sup>60</sup> For this point, see N. Luhmann, 1988, p. 14.

<sup>61</sup> Without pursuing this point further it can be said that elements of the system produce new elements in an autopoietic way, when they manage to "recursively regenerate, maintain and recover the same complex of processes that produced them", through their interactions. See, in details, M. Zeleny, "Autopoiesis: A paradigm Lost?" in M. Zeleny (ed.), *Autopoiesis, Dissipative Structures, and Spontaneous Social Orders* (Westview: Boulder, 1980), p. 4 and also the definition of autopoiesis in G. Teubner, 1993, p. 22.

<sup>62</sup> For this difference, see N. Luhmann, 2004, pp. 195-196.

<sup>63</sup> For a brief summary of this debate, see E. Christodoulidis, 1998, pp. 89-90.

<sup>64</sup> Also, because of their unique function as it will be shown in the course of the discussion.

As the legal system is by necessity linked with its environment, it cannot be indifferent to this intensification of the environmental complexity. To put it simply, since the law communicates *about* its environment, the very possibility of this communication is rendered more difficult against an environment that gradually becomes more complex. The law needs to mobilise counter-measures to deal with that complexity; otherwise, it would not be able to keep up with environment complexity and progressively it would stagnate. The very survival of the legal system necessitates an internal reaction.

What the legal system does in order to counter this problem is to intensify its internal complexity, in an attempt to become more able to accommodate external complexity.<sup>65</sup> As one would expect, this happens at the level of programming. The law elaborates its internal structures, by providing new distinctions, new concepts and new norms and by constantly reassessing the selections that control particular linkages between communications. It is only through this internal process that the law tries to deal with the intensification of external complexity and to ensure that it will keep communicating about its environment.

What this process implies is that a variety of modes of dependence or independence between the system and the environment exists, since it is never the case that internal complexity totally mirrors external complexity. This is because the potential for the intensification of internal complexity is inherently *limited*. Whatever happens within the system is ultimately oriented to the founding and unchallenged guiding difference; as this is the corner stone of the identity of the system, it designs the outer limits of what the system can do. Therefore, even if at the level of programming the legal system can be flexible, keep changing and become more and more complex, this flexibility cannot overcome the outer limits that the coding itself defines. No matter how internally complex it may be, the law will keep observing the world *as law*, only by employing the distinction between legal and illegal. If it would attempt to overcome this basic distinction it would simply cease to be law and from the point of view of the legal system this would be inconceivable. Accordingly, the elaboration of its internal complexity can never exceed the limitations that its code poses, because that would amount to a loss of the system's identity.

It follows that a problem of equilibrium is always present, namely a problem of balancing the ability of the legal system to cope with its complex environment, while ensuring the continuation of its distinct identity. In system-theoretical terms, this

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<sup>65</sup> For the indispensable unity between internal and external complexity, see N. Luhmann, 2004, p. 113.

problem has been recast as the need to find a balance between *redundancy* and *variation*.<sup>66</sup> Through *variation*, the system constantly adapts to the complexity of its environment; it perceives new stimuli, it organises new selections of what counts as relevant and it uses new externalities as triggers for its internal structuring. In other words, it becomes more sensitive to constant environmental surprises and deals with them. On the contrary, through *redundancy*, namely through reducing the element of environmental surprise by replicating what is already known and assessed by the system,<sup>67</sup> the system keeps limiting what can be selected as new information. In effect, redundancy is a mechanism that tends to eliminate the need for further information and filters out surprises;<sup>68</sup> simultaneously, it is presumed whenever something ends up as new information because only as a drift against redundancy can information exist – in this sense, redundancy is constantly present in all the operations of the system in a “shadow” form. In doing this, redundancy limits the diversity of operations that a system can identify as its own (variation). As a result, it ensures the continuation of the system’s identity by building up a kind of internal “memory” that serves as an internal horizon of reference for the accepted new selections. This horizon stabilises the accepted degree of the sensitivity of the system. In law, this is crystallised in the use of legal *concepts*, legal *principles* and legal *rules*;<sup>69</sup> in all these “historical loci” the law invests previous experience, enables access to previously tested and used distinctions and simultaneously condenses and generalises information for future use.<sup>70</sup> Through the establishment of a memory, it is ensured that the legal system is always bound to the legal coding and that the amount of surprise and environmental complexity that it can absorb through variation although wide is ultimately limited. Another notion for describing the same thing is *consistency*: whatever the amount of variation, the internal memory of the system is constantly referred to and always determines what and how will be processed.<sup>71</sup>

<sup>66</sup> For an introduction to the systems-theoretical use of these concepts, see N. Luhmann, 1995b, pp. 291ff.; also, more generally H. Atlan, “Noise, Complexity and Meaning in Cognitive Systems” (1989) 3 *Revue Internationale de Systemique* 237.

<sup>67</sup> For this point, see S.C. Smith, p. 198; also N. Luhmann, 2004, p. 320, where he argues that redundancy essentially “involves the information that is available for the processing of information, and variety is the information that is as yet missing”.

<sup>68</sup> Indeed, through redundancy the law manages to filter out a wide range of environmental information as totally irrelevant.

<sup>69</sup> It has to be stressed that these loci of legal memory develop primarily in the process of legal argumentation. For further analysis, see N. Luhmann, 2004, p. 328 and pp. 340ff.

<sup>70</sup> For the notion of “condensations”, see S.C. Smith, 1995, p. 196 and also N. Luhmann, 2004, pp. 340-341.

<sup>71</sup> See N. Luhmann, 2004, p. 183, with the caveat that consistency is used here in a technical sense and not in accordance with its use in mainstream legal theorising.



An illuminating example of the interplay between redundancy and variation within the legal system is the process of judicial argumentation.<sup>72</sup> The judiciary has to decide the exact application of the code on a case-by-case basis, as social conflicts that originate from the environment of the law are litigated and thus enter the legal system.<sup>73</sup> In dealing with them in their uniqueness, the judiciary is forced to distinguish between similarities and dissimilarities,<sup>74</sup> between what should count as new and what simply replicates what already exists.<sup>75</sup> As a result, the judiciary constantly draws distinctions and argues accordingly.<sup>76</sup> In order to do so redundancy is needed;<sup>77</sup> only a negotiation with the memory of the system allows for the possibility of establishing particular connections between cases, of articulating the dissimilar cases as such and of considering whether their being different justifies a departure from previously established rulings. In the case of adjudication, this negotiation takes the form of a quest for *reasons* that, instead of providing a “right” answer,<sup>78</sup> are used to justify insistence or departure from a previous decision.<sup>79</sup> Once this departure is established, however, the variation of the legal system intensifies and the system is forced to change and to become more sensitive to the possibility of creating an exception to pre-existing rules.<sup>80</sup> Of course this is an inherently contingent process, which is nonetheless non-arbitrary. This is because a certain amount of consistency is present in the process, primarily because of the need to guarantee that the legal system appears as a unity in time and not as the random sum of unrelated decisions.<sup>81</sup> In any case, as soon as a particular change becomes (through repetition in future decisions) stabilised, it grows to be part of the memory of the system and what

<sup>72</sup> Let me stress, here, that for Luhmann judicial decision-making is an organized, decision-making subsystem of the legal system. See, in details, 2004, pp. 158ff.

<sup>73</sup> For further analysis of the notion of conflict and its relation to law, see E. Christodoulidis, 1998, pp. 96ff., with further references and also, G. Teubner, “Juridification – Concepts, Aspects, Limits, Solutions” in G. Teubner (ed.), *Juridification of Social Spheres* (Berlind: de Gruyter, 1987), pp. 3-48, at pp. 7-8.

<sup>74</sup> Another way to describe the same think is through the judicial use of the symbol of equality. For this point, see N. Luhmann, 2004, pp. 134-135.

<sup>75</sup> This is achieved as a second-order observation, namely as an observation of the possible ways of applying the code (therefore of observing the world at the first level); in this respect, decision-making and argumentation are processes for the self-observation of the legal system, through the elaboration of the differences between cases. See, in details, N. Luhmann, 2004, pp. 305ff.

<sup>76</sup> See S.C. Smith, 1995, p. 192, where he argues that the development of the common law is based on the constant drawing of distinctions.

<sup>77</sup> See N. Luhmann, 2004, p. 318.

<sup>78</sup> It has been argued that this is simply an adjudicative pretence, in terms of which legal reasons are employed to provide authoritative, right outcomes. For this point, see S.C. Smith, 1995, p. 192.

<sup>79</sup> This thesis implies a particular systems-theoretical theory of legal reasoning. A complete analysis of such a theory, which perceives argumentation as a *preparatory* process and insists that legal rationality is a *local rationality* that cannot guarantee abstractly right solutions can be found in N. Luhmann, 2004, pp. 313ff and 1995b, *passim*.

<sup>80</sup> Accordingly, the exceptions are crucial for the modification of the law, as explicitly stated in N. Luhmann, 2004, p. 328.

<sup>81</sup> So the need for consistency may be seen as an additional condition of the unity of the legal system. For this point, see N. Luhmann, 2004, p. 319.

was once an instance of variation is (for the future) part of the system's redundancy.<sup>82</sup> An interesting side effect of this is that even decisions that at the point of deciding may be perceived as errors (namely as disruptions of the legal selections that have been –until then- established through redundancy)<sup>83</sup> become part of the matrix of the system and therefore can determine future decisions.<sup>84</sup>

Consequently, redundancy and variation are in essence the two sides of the same distinction and the one presupposes the other.<sup>85</sup> At the same time, their interplay is a constant source for internal instability, since it opens up the contingent possibility of something to be considered as a new piece of information. This contingency is necessary: it is the price that systems have to pay in order to remain operational against an increasingly complex environment. That is why in highly complex systems, like the legal system, the need to ensure both variation and redundancy is reflected in the *institutional* structure of the system,<sup>86</sup> namely in the formation of a particular institution (the judiciary) with the power to decide about the application of the code against a constant flow of environmental stimuli.

Let me summarise: the systems absorb environmental complexity by intensifying (at the level of programming) their own, internal complexity. This is essentially a limited process, which ultimately depends on the unchangeable nature of the legal code and which becomes substantiated as the outcome of the balance between redundancy and variation. According to this scheme, the legal system becomes operational, generates communication and combines its essential closure with a certain environmental openness. Nevertheless, this edifice assumes that somehow the system –and especially a closed system- is able to perceive its environment, at least as an under-defined “entity” beyond itself. The analysis so far has insisted that this is necessary for the system, but it has not shown how this can actually be happening. The next section is going to tackle exactly this problem.

<sup>82</sup> For an excellent presentation of this process, although not from a systems theoretical perspective, see E.H. Levi, “An Introduction to Legal Reasoning” (1948) 15 *The University of Chicago Law Review* 501. Levi uses the notion of “danger” as an example of change and stability in terms of common law reasoning.

<sup>83</sup> It is in this context that logic has a special function in adjudication: it organizes redundancy by rendering possible the identification of errors, since otherwise all errors would enter the matrix of the system. See N. Luhmann, 2004, p. 352.

<sup>84</sup> This happens because it is impossible to achieve an absolute consistency between decisions and therefore a space for tolerating mistakes must be allowed. See N. Luhmann, 2004, p. 91 and for a very similar point (regarding judicial mistakes), R. Dworkin, *Taking Rights Seriously* (London: Duckworth, 1977), pp. 118-123.

<sup>85</sup> That is why they can increase simultaneously and also why it is their combination that deepens the internal complexity of the system. See, in details, N. Luhmann, 2004, pp. 321-322 and p. 333.

<sup>86</sup> See S.C. Smith, 1995, p. 200.

**d) Interrelation of systems through interference and structural coupling.**

So, social systems need to perceive their environment. How is this likely to happen? The answer must be given at two distinct levels: the first level is fundamental and it refers to the very possibility of the existence of differentiated communication within the general communicative universe.<sup>87</sup> The second level is more concrete and refers to the possibility of the interaction between particular social systems,<sup>88</sup> but still presupposes the more fundamental level. This is where one has to start.

Social systems are sensitive to their societal environment because both they and their environment consist of communications, which are all *meaning-related*. The “stuff” of the societal universe is communication and although differentiated systemic communications generate a particular type of meaning, all social systems utilise essentially the same medium. One could say that at the background of each meaning-related system there exists as a constantly lingering structure, the pool of general meaning. Meaning is diffused at the societal level. All differentiated systems “participate” in this underlying structure and through this participation they become constantly aware of the existence of something beyond their concrete boundaries. A possibility to describe this underlying common structure is through the involvement of language as structure: all meaning-related systems are “mirrored” in general language. In effect, they participate in it and because of that they share the medium of meaning with other systems. Even if this tentative linguistic proposition can be seen only as a metaphor, the crucial point remains the commonality of the medium. This ensures that a fundamental *interference* between all types of meaning and accordingly of all social systems is indeed possible.<sup>89</sup> In the social world, meaning as a medium is over-pervasive, even though outside the tight grip of systems it remains under-determined. This over-pervasive presence generates a general communicating network (in essence, society), only within which can distinct social systems evolve.<sup>90</sup> Law as a social system takes part in the network of general social communication and therefore, shares the medium of meaning with the other social systems.

So, it is meaning as an underlying structure that ensures that social systems can be aware of their environment through interference. But does this mean that they can

<sup>87</sup> Accordingly, I am going to discuss only how systems perceive society and other societal systems as environment and not how they perceive the world of living and psychic systems.

<sup>88</sup> From the point of view of any system this is always an interaction between system and environment and not between systems. Systems cannot perceive other systems as such, but only as environment.

<sup>89</sup> For the notion of interference see in details G. Teubner, 1993, pp. 65ff. and 86ff.

<sup>90</sup> See N. Luhmann, 2004, pp. 89-90.

perceive their environment as something distinct and even more, can they receive signals from the environment and then produce relevant responses? This is a question that not only grasps the core of the relationship between system and environment, but is also crucial for understanding regulation, which, at least according to the open systems approach, should be seen as a systemic operation that relates directly the system with the environment.

The situation here is indeed complicated. Social systems are closed systems and they perceive everything according to their binary code. True, they are aware of their environment because of interference; however, they can make sense of it only by applying their code and by doing so they refer back to themselves. This is a kind of a vicious circle, which seems to exclude the possibility of interaction. But then again, systems have to take into account their environment otherwise they would cease to exist. Once again, the question comes to the surface: how is this possible?

The answer can be found only if one totally abandons the open systems paradigm and in its place employs a set of concepts that are suitable for analysing the interaction between self-referential systems. So, instead of concepts like input and output, it is indispensable to use *noise*, *irritation* and *perturbation*; and against the possibility of direct interaction, one should consider the possibility of *structural coupling*. Let me explain what these concepts entail and how they can help us to re-assess the interaction between system and environment.

According to systems theory the environment cannot provide signals that any social system can readily integrate. This would contradict the closed nature of the system's code. Rather, and especially as far as the law is concerned, the environment can be perceived as such only as *noise*, namely as the undifferentiated "something" which rests beyond the boundaries of the legal system. It follows that this noise can only stimulate the system in the form of *irritation* and not as a distinct, meaningful signal. It goes without saying that it is the system and only the system that determines what even counts as an irritation.<sup>91</sup> Given that some irritation is registered, this may generate a kind of perturbation<sup>92</sup> within the legal system, which forces the system to respond. The only possibility for such a response is, of course, the production of system-specific communication, namely a legal communication based on the application of the code. Therefore, the legal system responds to the environmental noise, by generating legal

<sup>91</sup> See N. Luhmann, 2004, p. 383, where he argues further that systems must show a kind of internal preparedness to be irritated.

<sup>92</sup> For this concept, see in details G. Teubner, 1993, p. 35.



communications and thus it is (once again) simultaneously open to its environment (because it reacts to the noise) and closed to it (because it processes it according to its code). This is how the law achieves system-specific order from noise<sup>93</sup> and manages to register environmental stimuli.<sup>94</sup>

Of course, the system needs to be able to perceive the environment even as noise. Even this minimal perception may be still problematic, given the indispensably closed nature of the code. However, this difficulty is overcome because systems are able to develop internal structures, which are compatible with structures of other systems belonging to the environment. This potential compatibility of structures opens up the possibility of what is usually depicted under the term “*structural coupling*”. The notion indicates that within the general social system (and this is linked with interference), several systems may be engaged in a parallel processing of information against a concrete social “event”, which is shaped as such exactly because of the multiplicity of systems that take part in this processing.<sup>95</sup> Of course, the very identification of such an event is a matter of observation that again is system-specific. Yet, what is crucial is that what is treated as relevant information by one system, is *simultaneously* understood as environmental noise by another. This is likely to happen especially when the latter system has integrated into its structures the need to rely on some environmental features on an ongoing basis.<sup>96</sup> Of course this need depends on system-specific, internal selection. However, and especially when systems functionally aim at providing triggers towards other systems or at receiving triggers from them, they tend to construct “opportunity” structures compatible with each other, in a patterned and time-enduring manner. When this is the case, a processing of information happens in parallel within systems: in systems-theoretical terms, a structural coupling is occurring and an indirect inter-systemic link is achieved.

Let me clarify this by providing an example from the sphere of medicine. Let's assume that a failed medical operation can be attributed to a mistake of the doctor in charge. Both the legal system and the system of the medical profession have structures that can deal with this as relevant information: the law deals with it as an instance of medical negligence and the professional system (possibly) as an instance of serious professional misconduct that results in disciplinary measures. These structures are very

<sup>93</sup> This phrase originates from H. von Forster's, “On Self-Organising Systems and their Environments” in M.C. Yovits and S. Cameron (eds.), *Self-Organising Systems: Proceedings of an Interdisciplinary Conference 5 and 6 May 1959* (Oxford University Press, 1960), pp. 31-50.

<sup>94</sup> For a detailed presentation of this process, see W.T. Murphy, 1994, p. 258.

<sup>95</sup> For this possibility, see G. Teubner, 1993, pp. 62-63.

<sup>96</sup> See N. Luhmann, 2004, p. 382.



much compatible: the same “event” can be simultaneously processed by both systems and thus to count (from the perspective of a given system) not only as a system-specific information but also as environmental noise that can be registered.

The obvious consequence of this formulation is that the more constant the establishment of common structures, the easier the possibility of interaction between the systems. On the contrary, if systems do not develop compatible structures for processing information, the possibility of registering that another system is processing information, even as noise, is much more problematic. This means that structural couplings facilitate the interaction between systems, but by doing this, they simultaneously reduce the range of it: only what the structural couplings allow is actually allowed. Everything else is excluded and cannot be registered at all.

Through the combination of interference and structural coupling social systems can perceive environmental stimuli and, therefore, can remain open to their environment. From then on, of course, closure re-appears and the legal system internally selects how it is going to react and what it will filter out.<sup>97</sup> Systemic communication is always system-specific communication. In the legal system, this results in a tautology: legal communication is always legal communication.<sup>98</sup>

## 2) The function of law.

The long previous section provided an account of some of the main concepts that systems theory is using in describing law as a social system. In this section, I will discuss another aspect of the systems-theoretical approach to law, namely the function of the legal system. It is a basic tenet of systems theory that social systems emerge in order to carry out a *unique* function within society. The insistence on this functional uniqueness is justified by a vision of modern society as a *functionally differentiated society*.<sup>99</sup> For systems theory, the distinct mode of the organisation of modern society is the emergence of a plurality of social systems that are differentiated as autonomous systems, exactly because they carry out a societal function that no other system does. The uniqueness of this function, in combination with the uniqueness of the code, gives to each social system its distinct identity. More importantly, it is exactly because of the uniqueness of their

<sup>97</sup> For further details, especially in terms of the structural coupling between the legal and the scientific system, see N. Luhmann, 2004, p. 116.

<sup>98</sup> A tautology that is of course unfolded at the level of programming!

<sup>99</sup> For this idea, see in details, N. Luhmann, *Political Theory in the Welfare State* (Berlin: de Gruyter, 1990), pp. 30-31.

function that the emergence of social systems can be seen as an *achievement*: since the function establishes the identity of systems, it is on the basis of their function that systems manage to reduce the complexity of the world in their own particular manner. To go back to the discussion in Part (B), this systemic functional differentiation is in itself a reduction achievement.

By defining the function of the system as unique one must be careful in distinguishing between *function* and *performance*. The former refers to the link between the system and society in general, while the latter to the relationship between social systems.<sup>100</sup> In other words, the term “function” designates what the system does towards society, whereas “performance” what it does towards other systems. Keeping this distinction in mind, one may observe several different tasks that systems execute;<sup>101</sup> some of them overlap, some do not. As far as performances are concerned systemic overlap is not problematic. On the contrary, functions never overlap: they are unique and as such, determine the identity of social systems.<sup>102</sup>

As far as the legal system is concerned, the distinction between function and performance is itself operative within the system in many ways. Yet, what is crucial is that the distinction enables us to abandon a wide range of proposals regarding the function of law,<sup>103</sup> as belonging to the domain of performance. For instance, dispute resolution, social control, social integration etc. are all important achievements towards which the law undoubtedly contributes, but these are in effect legal performances, since they merely designate possibilities for the orientation of law towards other systems and since other systems are also mobilised in achieving the same aims. The existence of systemic “equivalents” undermines the plausibility of considering these “functions” as uniquely legal. For instance, if the function of law were to increase social control, one would have to consider that the same assertion is equally plausible as a description of the political system. If this was the function of the law and given that the function, within a functionally differentiated society, must be unique then this assertion would only make sense as advocating the unity of the legal and the political system into one social system. Nevertheless, this is an erroneous conclusion: the law and the political system are two

<sup>100</sup> For this distinction, see N. Luhmann, 2004, pp. 167ff.

<sup>101</sup> For a definition of what may be understood as “task”, see N. Luhmann, p. 85.

<sup>102</sup> The idea of the uniqueness of the function differentiates significantly systems theory from traditional functionalist theories that insist on a kind of functional “pluralism”. For a very sophisticated model of the latter, see R. Merton, *Social Theory and Social Function* (New York: Free Press, 1968), especially his very detailed discussion regarding manifest and latent functions, dysfunction etc. It goes without saying that we are dealing here with two totally different perspectives on what the concept of function entails.

<sup>103</sup> For a detailed presentation of such proposals, see J. Raz, “On the Functions of Law” in A.W.B. Simpson (ed.), *Oxford Essays in Jurisprudence* (2<sup>nd</sup> Series, Oxford: Oxford University Press, 1973), pp. 278-304 and R. Cotterrell, 1992, pp. 71ff.

distinct social systems. However, this problem is solved if one considers social control as a performance that may be rooted either at the legal or the political system. Similar examples are countless.

The unique function that the legal system performs in society is a particular *generalisation of stable normative expectations*. Through the constant production of legal communications, what the law does is to stabilise *normative expectations*, namely behavioural expectations that do not cease to exist even in the case of disappointment. In this respect, normative expectations are different from cognitive expectations.<sup>104</sup> The latter are forced to change, when their content is countered by factual experiences: cognitive expectations *learn* from disappointment. This is not the case with normative expectations. Even when things do not go according to what is normatively expected, the relevant expectations remain valid. The disappointment does not have any impact on the content of normative expectations, which are able to resist counter-factuality. It is this feature of normative expectations that allows them to integrate dissent and disagreement and also to stabilise what should be expected as a normal course of future events. This does not mean that normative expectations cannot change (whenever the legal system deems this to be useful), only that they are not forced to change when their content is not actually met.

The law not only generates normative expectations; it also *stabilises* them. This means that the legal system ensures that some sets of normative expectations will be certainly sustained, *at the expense of others*.<sup>105</sup> The law achieves that by generating legal norms that take the place of loose societal norms. In that way it counters the proliferation of disorganised and inconsistent norms and it stabilises a dense network of institutionalised normative expectations, controlled as normative from within the system.

The law stabilises normative expectations in three distinct dimensions, namely the temporal, the social and the material dimension. It does that in a *congruent* manner, simultaneously in all these dimensions; it is their combination that guarantees the uniqueness of the legal function and that is why these dimensions require further attention.

The stabilisation of expectations in the temporal dimension is inherently linked with the normative nature of legal expectations. What this means is that legal normativity is transferred into the future, by reappearing in future legal communications. To provide

<sup>104</sup> For this difference, see N. Luhmann, 2004, p. 149 and E. Christodoulidis, 1998, pp. 121-122; for the origin of the idea, see J. Galtung, "Expectation and Interaction Processes" (1959) 2 *Inquiry* 213.

<sup>105</sup> This statement implies that in society there exist countless normative expectations, without them necessarily being legal. For further analysis, see N. Luhmann, 2004, p. 151.

an example: a present legal expectation produces a legal claim that will be tested in the future. Then, it may be fulfilled or disappointed, but in both cases the normative expectation will remain unchallenged and will provide a new legal claim relevant to whether the expectation will have been fulfilled or disappointed.<sup>106</sup> In this respect, legal normativity has been transferred between two points in time and the legal system succeeds in binding the future by providing presently normative expectations.<sup>107</sup> It follows that all legal communications are future oriented communications that communicate not only about what is now legally approved, but also about what *will be* approved. As legal communications integrate normative expectations, they link the present with the future and they determine in advance the state of the system that the next communication will face. In a sense, this is the main reason why the law employs normative expectations: only their ability to ignore the possibility of counter-factuality is able to achieve the present binding of the future.<sup>108</sup> Of course, since every systemic operation is constructed internally, the very perception of the temporal dimension is just a perception of time constructed by the legal system. The distinction between present and future is itself a legal distinction and it is against this distinction that it makes sense to talk about normativity.

In the social dimension, the legal system stabilises expectations by breaking up the individual context of concrete social interactions and by providing abstract generalised expectations, which are normatively valid no matter the identity of the individuals involved in an actual interaction. The law does that by involving abstract third parties into concrete interactions, namely by making sure that even non-participants would normatively expect exactly the same thing that the actual participants in an interaction would expect. To provide an example: whenever a legal sale is involved, it is expected by the parties involved that an amount of money will be paid. However, through the law this expectation can be socially generalised. Anyone, by simply observing this transaction will have exactly the same expectation of money exchange.

Finally, the law generalises expectations in the material dimension, in the sense that it manages to provide expectations for a plurality of concrete interactions. It achieves that by being a highly complex system, which is simultaneously closed but also very sensitive to its environment. This sensitivity is exemplified through a constant

<sup>106</sup> For further analysis of this example, see E. Christodoulidis, 1998, pp. 121-122.

<sup>107</sup> This is what is meant, by the rather abstract statement that the law achieves to bind time through normative expectations. For further analysis of this point, which is inherently linked with the possibility of meaning itself to bind time, see N. Luhmann, 2004, pp. 144ff.

<sup>108</sup> See N. Luhmann, 2004, p. 146.

sophistication of its internal apparatus. The law becomes more and more complex, by generating further secondary distinctions, new themes and concepts, new and more detailed norms and structures etc. This process can be depicted as a process of “thematisation”, since this internal sophistication of the normative horizon of the law ultimately determines the themes or the subjects, in reference to which law generates normative expectations. This ability for thematisation is essentially linked with the notion of variation and is achieved at the level of programming, which I have already discussed. What is crucial is that through a constant elaboration of its internal complexity, the law becomes more able to deal with external complexity and as a result to provide expectations for a very wide range of interactions. It is this ability that ensures the potential of the law to (legally) communicate about the world.

An additional point is necessary, though: the legal system generalises normative expectations but in order to do so a precondition must be met. Notably, what must constantly be ensured is that it is normatively expected that the expectations of the legal system are normative; in other words, a prerequisite of the normativity of law is that it is itself normatively expected. Only this *second-order normativity* achieves the institutionalisation of law and its high ability of stabilising normative expectations, not as ad hoc phenomena but as constant sources of resistance to disappointment. Without second-order normativity, it would not make sense to have expectations based on law; law itself cannot guarantee that the expectations that it generates will be met, but still it must somehow guarantee the continuity of its function.<sup>109</sup> This is achieved in a reflexive manner, through a general normative expectation of law’s normative nature.<sup>110</sup> Consequently, and as a final point about the function of law, it can be claimed that the legal system as a whole “operates on normative expectations of normative expectations as its secure base”.<sup>111</sup>

Let me conclude this section by linking the notion of function with the discussion regarding redundancy and variation. There, I argued that a balancing exercise is always at play between the two, so that the law can become more compatible with its complex environment without losing its identity as a distinct social system. What this statement leaves concealed is precisely how this balancing exercise can be achieved and especially what is the criterion that reveals when variation has gone too far. Through the notion of function this omission can now be repaired. The law can increase its variation

<sup>109</sup> See N. Luhmann, 2004, p. 157.

<sup>110</sup> For this point, see in details E. Christodoulidis, 1998, p. 118.

<sup>111</sup> See N. Luhmann, 2004, p. 159.



*only as far as its ability to perform its function remains intact.* If this ability becomes undermined, for instance because the variation of the law has reached a level where very particular legal pronouncements are constantly produced that cannot be normatively generalised, then the very function of the law (and thus also the autonomous nature of the legal system) is in peril. In such a scenario, mechanisms of redundancy become operational in order to counter the threat. This does not mean that redundancy will always achieve this task. However, further analysis must be postponed for the next part of this chapter.

### 3) Interim conclusions.

With the presentation of the function of law, I have concluded my long exploration of the nature of law as a social system that reduces complexity. Against this theoretical background, an interim conclusion can already be reached, a conclusion that comes as the necessary consequence of the main tenet of this theorising that law is an autopoietic, self-referential system. Any delineation of medical law as a distinct discipline constituted in accordance with a subject matter that belongs to the sphere of medicine, *namely to an external point of reference that as such organises the discipline*, underestimates the internal nature of everything that the law does. Indeed, these delineations fail because they directly project an externality into the law. This is an important failure, which lies at the root of the problems that I have identified regarding the doctrinal propositions. Essentially, it is their failure to take on board the self-referential nature of the law that is ultimately “responsible” for their unconvincing conceptualisation of medical law; this would similarly apply to any other proposition that would attempt to perceive medical law in terms of external organising principles.

Once again, this is not to say that the relevant environment, in our case medicine, is insignificant for the law; nor does it mean that the constitution of medical law is not ultimately linked with the regulatory orientation of law towards medicine. I still insist that the constitution of medical law is the result of this orientation. What this conclusion reveals is that the law controls *exclusively internally* this regulatory orientation<sup>112</sup> and, therefore, that it is necessary to assess anew *how* this influences what is happening within the internal horizon of the law. Therefore, it is necessary to enrich our theoretical analysis by taking on board how regulation can be perceived in systems-theoretical terms.

<sup>112</sup> I must stress here that the exclusively internal nature of social systems advanced by systems theory, does not exclude the possibility of doing empirical research on legal regulation. Although such a criticism exists, it has been successfully rebutted in J. Paterson and G. Teubner, “Changing Maps: Empirical Legal Autopoiesis” (1998) 7(4) *Social & Legal Studies* 451, *passim*.

## D. On regulation.

### 1) Regulation in the political system.

During the course of my thesis, whenever I referred to regulation, I have used the concept in accordance with a “traditional” understanding of it. In summary, this is based on the idea of direct causality: a regulatory aim is identified, a means is employed in order to achieve the aim and the ultimate success of the regulatory intervention is judged on whether the aim is achieved. If it is not, then an assessment of what went wrong can take place, on the basis of which new means are going to be employed.<sup>113</sup> When one takes on board the conceptual apparatus of systems theory, it becomes necessary to reassess the concept in a very different light. From the point of view of systems theory, the most fruitful starting point from which to discuss regulation is to make sense of it as an *operation of politics*. Taking this to be the fundamental premise, a set of issues comes to the surface all of which are oriented to a core question: how exactly can political regulation be conceptualised in systems-theoretical terms?

In order to answer this, one must start from an analysis of the political domain itself. Politics constitutes a just distinct social subsystem<sup>114</sup> within the general social system, namely the *political system*.<sup>115</sup> As such, it manifests all these features that ensure the self-referential character of any social system: it has its own basic binary code, namely the distinction between government and opposition;<sup>116</sup> it performs a particular societal function, namely the production of collectively binding decisions;<sup>117</sup> it is organised according to its own, internally constructed structures and elements, namely political decisions;<sup>118</sup> it builds internal complexity by generating further distinctions;<sup>119</sup> finally, it is a communicative system that constantly generates political communications according to its own linkage processes. Within such a framework, regulation is an aspect of

<sup>113</sup> For further analysis of this causal scheme, see R. Mayntz, “The Conditions of Effective Public Policy: A New Challenge for Policy Analysis” (1983) 2(1) *Policy and Politics* 123.

<sup>114</sup> This “just” implies that politics should not be understood as the center of modern society. Since the premise is that this is a functionally differentiated society it should be understood as center-less. For this point, see N. Luhmann, 1990, p. 31.

<sup>115</sup> For a detailed presentation of the political system as a social system, see N. Luhmann, 2004, pp. 357ff.

<sup>116</sup> For this distinction as the code of the political system, see N. Luhmann, 2004, p. 378. Another possibility is to employ the familiar distinction between friend and enemy as analysed by C. Schmitt in *The Concept of the Political* (Chicago: University of Chicago Press, 1996).

<sup>117</sup> See N. Luhmann, 1990, pp. 73-74.

<sup>118</sup> See N. Luhmann, 1990, p. 40.

<sup>119</sup> To provide an example, it often employs the distinction between progressive and conservative.

“performance” by which Luhmann designates the relationship between social systems. To put it more accurately, the concept of regulation captures how political communications at the operational level orient the political system to the other social systems, with the aim of affecting them in a particular way.<sup>120</sup>

Such a formulation of the issue inclines one to ask why this is the case and what are the reasons for such an operationalisation of the political system. Of course this is a very significant question; however, an attempt to answer it necessitates a thorough investigation of the internal complexity of the political system and this goes beyond the purposes of my argument. Going back to my discussion on juridification in the general introduction of the thesis, let us remember that it is the political aspirations of the “welfare state” that explain the regulatory orientation of the political system. Given the compensatory and claims-related nature of the welfare state,<sup>121</sup> the (at least rhetorical) realisation of the political inclusion of the populace<sup>122</sup> and the relevant inherent tendency to increase the themes that count as politically relevant, regulation appears as a dominant trend within the modern political system.

Leaving this explanatory task aside let me insist on the repercussions of perceiving regulation as an operation of the political system. The most important one is that regulation is determined internally, from within the horizon of the political system. It is only the political system and only through its own communications that defines the (political) goals that it deems necessary to pursue, the strategies that it is going to employ and the kind of results that it will classify as success or failure; this is so even if regulation is externalised and affects other systems. As far as the political system is concerned, the efficiency of its regulatory attempts is part of its communicative network: it deals with it by producing further (political) communications, which manage in a (political) way the reaction of the political system to the result that has been produced.<sup>123</sup>

This analysis already shows that it is mistaken to perceive regulation as a kind of direct, political steering of some areas of society as it is often assumed. In systems-theoretical terms the only steering that social systems can achieve directly is *self-steering*.<sup>124</sup> This is because the very concept of steering implies the minimisation of a difference

<sup>120</sup> In this respect, political performances are triggered whenever another system requires collectively binding decisions; this is a usual feature of the welfare state, where progress is measured by the increase in the quantity of performance. See, in details, N. Luhmann, 1990, pp. 74-76.

<sup>121</sup> For this point, see N. Luhmann, 1990, p. 23.

<sup>122</sup> See N. Luhmann, 1990, p. 34.

<sup>123</sup> According to such an understanding one could reach unexpected conclusions as to what counts as efficiency from an internal political point of view; for instance it can be the case that political efficiency simply means the elimination of external noise!

<sup>124</sup> See in details N. Luhmann, “Limits of Steering” (1997) 14(1) *Theory, Culture & Society* 41, p. 48.

between two different states of affairs.<sup>125</sup> Both what counts as a difference and what measures are taken for its minimisation can only be defined according to internal mechanisms; thus, the political system can only “steer” itself by defining the politically relevant state of affairs that has to be achieved and the strategies that it will employ to do that.<sup>126</sup> For instance, the welfare state creates such differences by considering basic values and by trying to eliminate the distance between what one has and what one desires in terms of these values.<sup>127</sup> It is of course highly probable and of course desirable that the self-steering of the political system will have an impact on other social systems; after all, regulation is a performance of the political system that attempts to orient the system towards the other sub-systems. Nevertheless, it is not the political system itself that determines what will happen within the other systems, but only these systems according to their own internal mechanisms. So, self-steering of the political system can have an external impact, but this ultimately depends on the self-steering mechanisms of the “receiving” systems.

Does all this mean that one cannot talk about regulation by simply considering what is happening in the regulated area? The answer is negative. It is possible to discuss regulation in this way. Yet, this can only be based on an observation that rests outside the domain of the political system and belongs to the system of social science. Such an external observation could investigate whether a regulatory attempt had actually an impact on the regulated field. Based on such an observation one can “objectify” the impact of regulation as a kind of congruence between the political desideratum (as this has been defined from the political system) and its contingent actualisation within the regulated field.<sup>128</sup> What is important, here, is that no causal scheme can explain this congruence. Only system-specific, internal mechanisms can determine whether this is indeed what is happening.

## 2) The notion of the regulatory trilemma.

So, where does this conceptualisation of regulation leave us regarding the constitution of medical law? Well, it represents the first step in understanding exactly how the law becomes oriented to medicine, an orientation that underlies the constitution of the

<sup>125</sup> See N. Luhmann, 1997, p. 42.

<sup>126</sup> For further analysis of the idea that this is the only aim that the political system can define as aim, see J. Paterson and G. Teubner, 1998, p. 457.

<sup>127</sup> See N. Luhmann, 1990, p. 105.

<sup>128</sup> Of course, this is not to say that the political system cannot itself observe this congruence; however, when doing so it will do it politically, in other words according to the range of alternatives that it internally generates.

discipline. In order to further this understanding more steps are necessary. The first is to identify the conditions of regulatory efficiency;<sup>129</sup> the second is to see exactly how the law fits into this perception of regulation.

Let me start by identifying the necessary condition for any attempt to regulate with any chance of success. It must be obvious by now that the answer lies in the logic of structural coupling. As I have already discussed, the only possible way for social systems to interconnect and have any impact on each other is through structural coupling, namely through a parallel processing of information facilitated by the existence of common structures. For any political decision to have any impact on any area of society, structural coupling is therefore indispensable. To provide an example, the efficiency of a political reform on education depends on the structural coupling between the political system and the education system.

However, this is an oversimplification of the picture. The political system never orients to the other subsystems in a “pure” manner; rather, its orientation is always *mediated* by the legal system. This means that although the political system originates regulation, it attempts to carry its impact into the regulated field through the involvement of the law. The law becomes a “medium” used by the political system.<sup>130</sup> Accordingly, regulation takes the form of legal prescriptions, which in turn are supposed to have the desired impact on the regulated field.<sup>131</sup> It is crucial here to stress that any legal prescription carries with it regulatory potential and is related to political goals. This is obviously the case with legislation, the passing of which can be seen as an “event” that exists simultaneously in both the legal and the political systems.<sup>132</sup> However, even judicial decisions and more generally the institution of adjudication co-operates in the process of regulation: they “complete” political regulation by dealing *ex post* with situations that the political system regulates *ex ante*. Additionally, when *novel* situations are adjudicated for the first time, then the (judicially generated) legal norms on the basis of which a decision is reached are indeed very significant from the perspective of regulation.<sup>133</sup>

By identifying regulation as legal regulation, the question of efficiency becomes more complicated. This is contingent not only on the coupling between the political system and the regulated field, but on a number of couplings that all must be successful.

<sup>129</sup> From then on, whenever I use the term “efficiency” this will mean the contingent congruence between the political desideratum and its actual impact on the regulated field.

<sup>130</sup> For this point, see N. Luhmann, 2004, pp. 363 and 370.

<sup>131</sup> See N. Luhmann, 1990, p. 82.

<sup>132</sup> Of course, this does not mean that these systems are not distinct, only that at the level of performance the two reciprocally cooperate quite often. For this intense cooperation, see N. Luhmann, 2003, pp. 403-412.

<sup>133</sup> It goes without saying that this is a very important characteristic of legal systems based on case law.



One can at least identify two additional couplings, namely the coupling of the political system with the legal system and, crucially, the coupling between the legal system and the regulated area. Now, the very close interconnection between law and politics establishes very solid structural couplings between the two and thus, what becomes crucial is the coupling between the law and the regulated field. Still, what must always be kept in mind is that if any of these couplings is unsuccessful, the “chain” of systemic interconnection is broken and the possibility of a regulatory impact is shaken.

In any case, structural coupling is the crucial concept here, even as a fundamental prerequisite for any regulatory attempt. The question, then, is how to integrate this concept into a theory of regulation on the basis of which the possibility of a successful regulatory impact can be secured.

The most fruitful attempt to theorise this has been provided by Gunther Teubner, in the analysis of the “regulatory trilemma”.<sup>134</sup> According to Teubner, when the law attempts to regulate three *detrimental* possibilities open up, each one of which can have a harmful effect on the actual impact of regulation. As Teubner puts it:

*“Every regulatory intervention which goes beyond these limits is either irrelevant or produces disintegrating effects on the social area of life or else disintegrating effects on regulatory law itself.”*<sup>135</sup>

In essence, what Teubner does is to identify two distinct problems.<sup>136</sup> The first is indifference, which can be equated with the lack of stable structural coupling between the systems. If no coupling is achieved nothing can happen: nothing is registered from the outside, no noise is perceived, and therefore the systems involved simply remain indifferent, being unaware of each other. It goes without saying that regulation cannot have an impact in the case of such indifference. However, even when indifference is overcome, a second problem may be present, namely that of disintegration. This term denotes the possibility that a successful inter-systemic interaction can have detrimental effects for the identity of the systems that participate in the interaction. For instance, if the legal system is successfully coupled with the educational system and keeps bombarding this system with legal prescriptions it is possible that the education system will lose its distinct character and in a sense become “colonised” by the legal system. Conversely, if the legal system provides prescriptions that are essentially determined by the rationality of the system under regulation, then it is the legal system that will be itself “colonised”. In the same example, if the relevant legal prescriptions are determined by

<sup>134</sup> See, in details, G. Teubner, 1987, pp. 19ff.

<sup>135</sup> See G. Teubner, 1987, p. 21.

<sup>136</sup> As far as the kind of problems that he identifies is concerned, it seems to me that he refers to a twofold distinction.

the concepts, the necessities and the rationality of the educational system the legal system can no longer sustain its distinct identity but only regulates as a replica of the educational system.<sup>137</sup> Having identified the problem in such a way, Teubner goes on to propose “solutions” to the trilemma that can guarantee that indifference is overcome and that the problematic disintegration is countered, notably the idea of “reflexive” law.<sup>138</sup>

What is very interesting about the notion of the “regulatory trilemma” is that it highlights the possibility of regulation having disintegrating effects. This means that when the law regulates a social domain, it becomes *exposed* to this domain and as a result it may suffer disintegrative effects. By logical necessity, the more the law becomes exposed the more possible it is for these disintegrative effects to materialise. In other words, the more the law is used instrumentally –and the concept of juridification is crucial here– the more it becomes susceptible to the peril of losing its distinct identity.

Admittedly, a paradox exists here. On the one hand, the law is the main means through which regulation is effected. On the other hand, as it becomes more and more instrumentalised and its regulatory range increases, its autonomous character is endangered. Still, the law does regulate and quite often the regulatory aims are achieved and the character of the law remains intact. This means that this paradox is somehow countered.

This is indeed the case, mainly because the law –like any other system– always strives to survive, in other terms to sustain its distinct character as a social system. This means that exactly because of the possibility of disintegration, the law has mobilised particular “mechanisms” to counter this effect. These mechanisms are structurally embedded in the legal system and we have already encountered them in the general discussion of systems theory: they are the combination of redundancy and variation that determine exactly how much the law will intensify its internal complexity, and the unique function of the law according to which it stabilises normative expectations. They constitute the law’s “defences” to the danger of disintegration, because they determine exactly *how the legal system will tolerate its regulatory exposition to the non-legal world*. This is not to say that this defence is always successful and that it is never the case that disintegration

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<sup>137</sup> For further analysis of this “colonisation” problem see also G. Teubner, “Altera Pars Audiatur: Law in the Collision of Discourses” in R. Rawlings (ed.), *Law and Economy* (Oxford: Oxford University Press, 1997), pp. 149–176, especially pp. 156ff. The discussion there relates the problem of disintegration with the so-called materialisation of law and the gradual penetration of substantive rationality into the formal legal rationality. In chapter 2, I already indicated that the empirical reality of medical law can be seen as exhibiting a surplus of substantive rationality – therefore, I will take up this issue again in the next chapter, where I will apply the theoretical ideas presented here directly to medical law.

<sup>138</sup> I will come back to these solutions at the penultimate part of this chapter.

happens. Rather, what these mechanisms guarantee is that quite often the law does manage to avoid disintegration.

The notion of the regulatory trilemma is designed with a specific aim in mind, namely to explore the problems that legal regulation entails and to push forward proposals on the basis of which legal efficiency can be enhanced. From this point of view, the mechanisms that I have just identified can be seen as *limitations* on what the law can achieve: by ensuring that disintegration is avoided they raise a barrier to the regulatory potential of the law. The law is not always doing what it is supposed to do: if the opposite were the case, then it would be impossible to avoid disintegrative effects. Accordingly, any attempt to enhance the efficiency of legal regulation has to take into account these limitations.

From the point of view of the main aim of my thesis, the realisation that the law reacts to disintegrative effects pushes forwards a different implication. Let me recall here that I am focusing on reassessing the constitution of medical law as a discipline and that I concede that this emerges in the process of the regulatory orientation of law to medicine. The underlying assumption here is that within the internal horizon of the legal system new disciplines emerge whenever the law attempts to regulate with some constancy a social domain previously unregulated. In this process the law filters out the possibility of disintegrative effects. In doing so, *it determines exactly its internal reaction to the environment under regulation*. Consequently, the mechanisms that control the manner of law's exposition to its environment, simultaneously determine how new disciplines will be structured. Essentially, a tautology is present in the last statement: whatever limits what the law can do in terms of a particular regulated field also determines how the law becomes internally structured in terms of a new discipline that emerges because of this new regulatory orientation. In the case of medical law, this means that the constraints that redundancy and variation and the function of law impose on what the law can achieve when regulating medicine also determine exactly how medical law is constituted.

In the next two sections, I will further explore my proposed link between the constitution of a discipline and the existence of limitations on the regulatory potential of the law.

### **3) Redundancy and variation revisited.**

I have already argued, with Luhmann and Teubner, that the combination of redundancy and variation manages the internal complexity of the legal system, as the environmental complexity increases. In essence, any call for regulation is itself an instance of such an increase and as such it necessitates an internal legal response. Through variation the law attempts to accommodate as much as possible the regulatory demands of the political system and crucially the complexity of the regulated area. However, this attempt is constantly checked in terms of redundancy, which can be seen as performing an "immunisation" task. It counters the extreme intensification of variation, by ensuring that some environmental signals will be left out and will not generate new information registered as such by the law. It is exactly in this respect that redundancy limits the regulatory potential of the law.

As far as the constitution of new disciplines is concerned the interplay of the two takes the following form. Through variation, elements of the legal system are linked together in such a way as to accommodate the new environmental stimuli (that emanate from the new regulated area). Then, new themes are added as legally relevant and new norms are produced that are more "compatible" (although this compatibility is defined internally) with the domain under regulation. This process indeed carries with it the danger of law being overburdened by the particular character of the regulated area. This burden is checked out through redundancy that links new information with old concepts, and distinguishes between accepted and not-accepted new themes. Through redundancy the novelty that a new regulated area brings into the law is tamed: instead of radical internal changes (that would be possible if variation was the only force in play), only moderate shifts take place. In a sense, redundancy represents the conservative aspect of the legal system, whereas variation is its progressive counterpart. Yet, it is only the combination of the two that establishes exactly how new branches of the law are organised.

### **4) The stabilisation of expectations in the temporal dimension.**

A second structural limitation refers to the function of law and in particular to the stabilisation of expectations in the temporal dimension. Once again this structural

limitation also determines how new disciplines are constituted because it defines the exact way of law's orientation to its environment.

The function of law is to stabilise normative expectations. It does so by binding time, namely by projecting presently constructed expectations into the future in such a way that future disappointments are to be resisted. In doing so, the law is based on its particular construction of time: not only does it define internally the distinction between present and future, but it also manages the so-called "double modality" of time. This term denotes the difference between how the present defines the way that the future will evaluate the present and how the future will actually define the present.<sup>139</sup> The law solves that in favour of the present; that is what the stabilisation of normative, counterfactual expectations achieves. My point, here, is that the particular temporality of the law presents two time-related limitations for regulation. These are inherently linked and can be seen as the two sides of the same coin; yet, for analytical purposes I will discuss them as distinct.

The first difficulty refers to the possible incompatibility between the law's temporality and the temporality of the other systems involved in regulation. By incompatibility I mean not only a possible difference between how systems define the distinction between present and future, but also a difference in the way that they manage the double modality of their internally defined time. As far as regulation is concerned, this is a particularly intense problem, because the political system is primarily a goal-oriented system, which is organised primarily on the basis of purposive programs.<sup>140</sup> In terms of the problem of double modality, this means that the political regulatory claim assumes a solution of the temporal difference in favour of the future. This contradicts the legal system's solution, which is significantly oriented to the present.<sup>141</sup> This problem is further intensified if the system under regulation (which has provided the original regulatory stimulus) also solves the double modality of time in favour of the future. Probably, the easiest way to identify this problem empirically is by taking into account the use of procedural delays by the legal system. Procedurally speaking, the legal system delays the final decision about particular disputes. In this respect, it allows for a very careful consideration of the exact way in terms of which its present state will bind the future. Through such delays, the "distance" between present and future is in a sense expanded and it is further guaranteed that it is the present that will define the future. In

<sup>139</sup> For this admittedly abstract distinction, see N. Luhmann, 2004, p. 199.

<sup>140</sup> See N. Luhmann, 2004, p. 198.

<sup>141</sup> One must remember that the law is not primarily a goal-oriented system, although it undoubtedly incorporates such features. See N. Luhmann, 2004, p. 184.



any case, what has to be kept in mind is that all the possible differences in time-perception cannot be totally accommodated by the legal system if it has to consider them seriously. Once again, the legal system is a closed system that obeys its own temporal logic. Therefore, it is possible that differences in the management of time will be filtered out by the law and in this respect will be neglected in the process of legal regulation and in the constitution of the discipline that emerges during this process. The new disciplines will be characterised by the legal dimension of time not by that of the area they regulate.

For the second problem, I have to turn back to the generalisation of normative expectations and especially to the element of stability that these expectations generate. The law achieves its function when it provides *stable* sets of normative expectations, in terms of which *stable* behavioural patterns can be established. Accordingly, even if normative structures can change (and this can indeed happen within the level of programming), the need for stability counters the degree of the frequency of change. What regulation necessitates, however, is exactly a change of some normative structures of the law. Because of the need for stability, one could expect a certain legal reluctance against change. Once again a balance is necessary between stability and change, between flexibility in responding to environmental stimuli and rigidity in the production of stabilised expectations. In a way this balance corresponds to the need of the legal system to be *internally efficient*, namely to be able to continue to carry about its unique function. Consequently, the law can accommodate the normative changes that regulation entails, but only when regulation does not stretch to an intolerable degree its potential to provide stable sets of normative expectations. This is particularly problematic in areas that evolve at a very fast pace (modern science is an obvious example), and in cases where the political system is under severe pressure to regulate instantly.<sup>142</sup> Because of this “speed”, constant calls for new regulation emerge that cannot be easily managed by the legal system, as this amounts to a constant reshaping of normative expectations. Accordingly, even when new legal disciplines emerge, it is not necessary that they will integrate the fast changes that occur in the areas that they are supposed to regulate. Even their novel character cannot escape the fact that the law will always lag behind the rapid pace of change exactly because of its task of *stabilising* expectations.

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<sup>142</sup> For this problem, see in details N. Luhmann, 2004, pp. 371-3, where he argues that the enactment of legislation is the devised used by the political system when immediate regulation is necessary.

### 5) The notion of reflexive law.

In this penultimate section, I want to include an additional dimension to the factors that determine the constitution of new disciplines within the law. This is a dimension of a different "type", because although it is once again rooted in Teubner's regulatory trilemma, it is not linked with the possibility of disintegration but with the crucial notion of structural coupling. This dimension is revealed through a tentative theoretical suggestion that has been developed with a particular aim in mind<sup>143</sup> This is to counter the pessimism that is usually associated with the systems-theoretical analysis of legal regulation and especially with the view that the systemic interaction between self-referential systems that regulation entails is more likely to be improbable than not.

The tentative suggestion to which I refer here is that this improbability can be overcome, by ensuring that constant patterns of structural coupling between the law and the system under regulation are stabilised. In order for this to be achieved, especially in a functionally differentiated society, a gradual emergence of a different "type" of law would be very promising. More precisely, the proposition is that the law has to become gradually *reflexive*, namely a regulatory agent that takes into account both its own boundaries and –crucially – the self-referential nature of the areas that it attempts to regulate. If this can be achieved then the possibility of a constant structural coupling between the law and the regulated system can be much more easily sustained.<sup>144</sup> Essentially, this idea of reflexivity acknowledges that the law can have only an indirect impact, which must be understood simply as the potential to open up the internal self-steering of the regulated area. So, against purely formal understandings, the law can hope to achieve regulatory aims; simultaneously, against substantive claims, the law cannot hope to achieve too much: it cannot dispense with its own structural limitations as to what it can itself process, nor can it neglect the autonomous character of the regulated area. Regulatory impact lies in the middle: the law can simply trigger self-regulation of society by self-steering. In other words it can regulate society, only by regulating itself.<sup>145</sup>

If this proposition holds –and indeed there exists a very intense theoretical debate within systems theory whether such reflexivity is possible–<sup>146</sup> then, the

<sup>143</sup> And in this respect, it has a very strong normative element.

<sup>144</sup> See G. Teubner, 1987, p. 121 and 1988, p. 218.

<sup>145</sup> See G. Teubner, 1993, p. 69.

<sup>146</sup> Against the view that this is the case, see N. Luhmann, "Some Problems with "Reflexive Law"", in G. Teubner and A. Febbrajo (eds.), *State, Law and Economy as Autopoietic Systems: Regulation and Autonomy in a New Perspective* (Milan: Giuffrè, 1992), pp. 389-415, *passim*. For an excellent presentation of the arguments in favour

constitution of new disciplines within the law will be further dependent on this concept of reflexivity. Essentially, it will be necessary to identify the reflexive elements that are present in these disciplines and through them to further investigate how exactly they take on board the self-referential nature of the domain that they regulate.

Starting from this general concept of reflexivity, the main proponents of reflexive law, like G. Teubner<sup>147</sup> and H. Wilke,<sup>148</sup> have further substantiated their claim by proposing particular models according to which legal reflexivity can be understood and used politically. All these models or types of reflexive law, aim at enhancing the possibility of stable structural couplings as a permanent achievement. If this possibility collapses, the successful interconnection between systems becomes precarious and even the modest aspiration of reflexivity would be in vain.

In essence, five modes of systemic interaction have been proposed in order to sustain the idea of reflexive law: *tangential response*, *mutual observation*, *coupling through interference*, *communication through organisation* and *synchronising difference reduction*.<sup>149</sup> All of these modes make use of the idea of reflexivity and attempt to enhance legal regulation, by ensuring that the law takes into account the self-referential character of the regulated area.

The mode of tangential response indicates that the law can attempt to regulate on a trial and error basis. Namely, the law should simply send out regulatory “signals” and then let the regulated system process these signals according to its own matrix of operations. It goes without saying that what will eventually happen is highly contingent. Yet, it is hoped that exactly through the contingent character of this trial and error process, it will eventually be realised what signals are registered successfully by the regulated system. On the basis of this realisation the legal system can then build enhanced structures focusing on these particular signals and therefore can stabilise systemic interrelationships through these structures.

The idea of mutual observation proposes that the legal system adopts a stance of second-order observation, according to which “it reconstructs the self-reference of the observed system”.<sup>150</sup> In doing so, the law attempts to integrate the self-reference of the regulated system into its own horizon and then to regulate accordingly. Of course, once

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of reflexive law, see J. Paterson, “Reflecting on Reflexive Law” in M. King and C. Thornhill (eds.), *Luhmann on Law and Politics: Critical Appraisals and Applications* (Oxford: Hart Publishing, 2006), pp. 13-35.

<sup>147</sup> See especially his 1993, pp. 64ff.

<sup>148</sup> For example see his “Political Intervention: Operational Conditions for Generalized Political Exchange” in B. Marin (ed.), *Governance and Generalized Exchange: Self-Organizing Policy Networks in Action* (Frankfurt: Bulder, 1990), pp. 235-254.

<sup>149</sup> I borrow this categorisation, from J. Paterson, 2006, pp. 25ff.

<sup>150</sup> For this idea, see G. Teubner, 1993, p. 80.

again it ultimately does so internally: what the law is able to perceive as the self-reference of the regulated system is necessarily based on the legal understanding of this self-reference. There is no guarantee that these two will coincide. Again then, an element of contingency is present. However, if such a coincidence is achieved, the possibility of structural coupling is ensured and the chance for regulatory success enhanced.

I have already analysed the concept of interference during my discussion in chapter 3. For theorists of reflexive law, interference is not simply a basic precondition of systemic interconnection, but rather an active “facilitator” of regulation. This is because it may highlight sensitive intervention points, in terms of which the regulated system can possibly attain a certain degree of compatibility with the regulatory aims embedded into the law.<sup>151</sup> Within this line of thinking, the example that is usually analysed is the so-called option policy: the only thing that the legal system can do is to provide options that through interference appear as intervention points against which the regulated area potentially reacts.<sup>152</sup>

The concept of communication through organisation implies that it would be possible for reflexive law to operate if at the boundaries between the law and the regulated area a kind of “binding” organisation could be formed. Such an organisation would aim at guaranteeing the parallel processing of information and ultimately the stabilisation of the conditions for systemic interaction.<sup>153</sup> An example of this kind of organisation is the so-called “intra-organisational juridification”, in terms of which “organisational processes are legally reconstructed in such a way that they themselves become sources of law”.<sup>154</sup>

Finally, a last possibility is to try to synchronise the difference reduction. This idea is related to the concept of steering and aims at ensuring compatibility on the way that the law and the regulated system minimise differences in their own way of achieving self-steering. If such compatibility can be achieved, the law and the regulated system can become enriched by common structures; in turn, these structures can ensure a very stable pattern of structural coupling and therefore of successful inter-systemic interaction.

Now, these are the proposed options for the operationalisation of the idea of reflexive law. While it still remains an open question whether these proposals are indeed plausible, they show a way out of the “crippling” closure of social systems. In the final chapter, I will explore some of these suggestions in the context of medical law.

<sup>151</sup> For this idea, see in detail J. Paterson and G. Teubner, 1998, p. 457.

<sup>152</sup> For this example see G. Teubner, 1993, pp. 93-95.

<sup>153</sup> See in more detail J. Paterson and G. Teubner, 1998, p. 477.

<sup>154</sup> *Ibidem*.

## E. Conclusion.

Let me end my discussion in this chapter, by providing a summary of what the theoretical endeavour attempted here brings forward. The constitution of medical law as a field has to take into account the self-referential nature of the law itself. As long as this is conceded, two inferences become inevitable. The first is that the doctrinal propositions regarding the subject matter of medical law are at the outset problematic because they are based on a set of assumptions that are not compatible with this self-referentiality. The second inference is that the conclusions reached in chapter 2 regarding the empirical complexity of medical law indeed signify something important about the constitution of the discipline.

Within these lines, my aim here was not to proceed to the substantial discussion of how medical law is constituted, but rather to provide a “platform” of conceptual tools on the basis of which this reassessment can occur. The backbone of this platform takes the following form: the regulatory orientation of law towards social domains that have so far been unregulated necessitates an internal re-arrangement of elements of the legal system that in effect results in the constitution of new branches (disciplines) within the law. The constitution of these disciplines is very much determined by the mode of the orientation of law to its environment. In turn, because this orientation exposes the legal system to its environment in a way that is potentially dangerous for the law because of the possibility of disintegrative effects, it is always determined by the mechanisms that are employed to counter these effects. Accordingly, it is exactly the same mechanisms, and namely the combination of redundancy/variation and the function of law, that ultimately determine how disciplines are constituted. Of course, the necessary presupposition only in terms of which new disciplines emerge is that a “sustainable” structural coupling between the law and the regulated area is achieved. In this respect, theories of reflexive law that expand our understanding of how this sustainability can further be achieved are also significant in the understanding of how new disciplines come into existence.

In the next chapter, I will apply this theoretical platform to medical law and I will show what conclusions can be reached regarding the constitution of this new legal discipline. Since all the theoretical work for this application is included in this chapter, I will conclude by providing an inventory of the key concepts that will be used in the discussion that follows. Naturally, this is only a very brief definition of some crucial



notions; for further analysis the reader is referred to the relevant sections in the body of this chapter.

**Basic distinction:** the binary conceptual scheme, on the basis of which systems generate system-specific meaning. This scheme constitutes the *code* of the system. In the case of the law this takes the form legal – illegal.

**Conditional programs:** the criteria on the basis of which the two sides of the basic distinction are concretely allocated. In law, these criteria are conditional, namely they are based on the fulfilment or disappointment of prerequisites; they can be constructed with purposive programmes, which are based on the achievement of particular aims.

**Function:** the notion that defines the unique “task” that any system performs within society. To be contrasted with *performance*, which denotes the link between systems.

**Normative expectations:** expectations that do not learn from disappointment.

**Observation:** the process in terms of which any system makes sense of the world through the application of its basic distinction.

**Operation:** anything that a system “does” in accordance with its mode of observation.

**Redundancy:** the mechanism on the basis of which systems build up their internal memory by constantly replicating what they already know. To be contrasted with variation.

**Reflexivity:** a notion that denotes either a) the ability of the law to be aware of its own limits or b) the possibility of the law being aware of the self-referential nature of the systems it attempts to regulate.

**Regulatory trilemma:** a notion that denotes the possibility that regulatory attempts can result in systemic indifference or in pathological (disintegrative) effects for the law or for the regulated area.

**Self-description:** a specific type of operation on the basis of which a system makes sense of itself.

**Structural coupling:** the necessary precondition of inter-systemic interaction. It replaces the input-output model advocated by the opens systems approach.

**Thematisation:** the mechanism on the basis of which systems enrich their internal apparatus so that they can connect in a more complicated manner with their external environment.

**Variation:** the opposite of redundancy, namely the mechanism that guarantees that systems can learn new information and incorporate this information into their programmes.

## **Chapter 4**

### **Medical Law In Search Of Its Object**

## A. Introduction.

My aim in this final chapter of the thesis is quite straightforward. What I intend to do is to go back to the discipline of medical law and to provide my own view on how this is constituted. I will do that on the basis of the theoretical platform provided by systems theory as presented in the previous chapter. According to the perspective I adopt, two theses emerge as the “building blocks” of the reassessment of medical law that I propose here. The first thesis is that it is the self-referential nature of the law that ultimately determines how medical law is constituted; thus, it is necessary to abandon propositions that define the object of an already constituted field and to investigate how medical law becomes projected as an autonomous branch of the law *internally*. Medicine cannot be used as a direct external reference, because from the point of view of the law it is simply part of its environment. It cannot be directly grasped as such, but only as external noise that triggers legal operations and ultimately legal communications. The second thesis is that medical law occurs as a result of the regulatory orientation of law towards medicine and therefore it depends on the particular systemic interaction between the system of law and the system of medicine. This remark necessitates an investigation of medicine as a social system and implies that the only plausible “definition” of a subject matter for medical law is exactly the link between law and medicine and nothing more.

Before starting the substantial analysis, let me clarify a point about a possible methodological objection. Because of the self-referential nature of all communication, even my own discussion regarding medical law does not take place from a privileged Archimedean point. Rather, it is just another system-specific observation based on the particular mode of observation innate to the system of science, on the basis of which “knowledge” about phenomena is produced. This sociological observation is external both to law and to medicine. In a sense this is a second-order observation,<sup>1</sup> since what is at stake is exactly to observe the way according to which the legal system observes reality,<sup>2</sup> in our case medicine. Accordingly, whatever I say here is just an external

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<sup>1</sup> For the concept of second-order observation see W.T. Murphy, “Systems of Systems: Some Issues in the Relationship Between Law and Autopoiesis” (1994) 5(2) *Law and Critique* 241, pp. 250-251.

<sup>2</sup> It is interesting to note here that the legal system cannot observe *how* it observes the world, since none of its distinctions can perform this task. If the opposite were the case, the same distinctions would be used both as means and as objects of observation and this would be paradoxical; in effect this “how” constitutes a “blind spot” for any system, a spot that cannot be internally observed. For further analysis of the idea of a “blind spot” that is assumed in any kind of observation see N. Luhmann, *Law As A Social System* (Oxford: Oxford University Press, 2004), p. 182 and M. Merleau-Ponty, *Le Visible et l'Invisible* (Paris, 1964), p. 172.

conclusion on what medical law is about. To replicate completely the legal or the medical point of view is indeed impossible given the sociological orientation of my discussion.

As far as the structure of this chapter is concerned, this follows the logical repercussions of the theoretical analysis in chapter 3. So, in the next part I will identify medicine as a social system, in order to clarify the nature of the inter-systemic interaction that triggers the emergence of medical law. Then, in part (C), I will discuss the general preconditions of the structural coupling between law and medicine that ensures that some interaction between the two can indeed take place. This is important, because if structural coupling cannot be achieved then law and medicine would be in a state of mutual indifference and thus, medical law would not exist. Having established the possibility of structural coupling, I will examine in some detail exactly how medical law becomes organised in the process of the legal regulation of medicine. This is going to be the subject matter of part (D), which will be based on my analysis of the interplay between redundancy/variation and the function of law and which will reassess both the doctrinal analysis and the empirical material of medical law. In this same part, a brief discussion on the significance of the suggestion of reflexive law for medical law will also be included. Through the synthesis of all these steps, my conclusion regarding the constitution of medical law will then be clearly stated.

## **B. Medicine from a systems-theoretical point of view.**

To begin to understand the domain of medicine as a social system I will refer the reader back to my introductory discussion in chapter 2, where I identified what legal norms are relevant for my investigation and presented a theory of how medicine should be understood. I argued that we should make sense of it as the “jurisdiction” of the medical profession, namely as that area of practice that members of the medical profession define as pertaining to their expertise. Although this definition refers to the notion of practice, equally important is its discursive element: it is of crucial significance how doctors perceive what they are doing. In further elaborating the idea, I insisted that medicine, understood as jurisdiction, could be further refined as integrating two distinct aspects. The first aspect, which I called the “technical” dimension of medicine, refers to the provision of care to patients and includes everything that requires technical expertise and medical knowledge; essentially, it refers to the tasks that doctors perform under their professional capacity. The second aspect, which I depicted as the “institutional”



dimension of medicine, is related to the particular institutional arrangements that underlie the availability of medical care and refers to the financial and administrative side of the everyday provision of medical services.

In revisiting this initial idea from a systems-theoretical point of view, I am suggesting that this differentiation of medicine as jurisdiction into two aspects is not simply an analytical distinction that can be useful for descriptive purposes only (even though this is exactly how I used the distinction in chapter 2). Rather, this distinction has further significance, since it shows that what we can ostensibly identify as a unified social phenomenon involves at least two distinct social systems. The technical aspect of medicine belongs to the system of science, whereas the institutional aspect is closely tied with the economic system. This proposed disaggregation into two different systems does not entail that the two aspects of medicine are totally isolated or that only through this distinction it makes sense to speak about medicine. The technical and the institutional aspects of medicine are not two completely separate structural blocks within the edifice of medicine; rather they are intimately interwoven, being simultaneously relevant whenever a particular instance of the practice takes place. For instance, whenever a medical operation is performed (technical aspect of medicine), it is co-determined by the administrative arrangements of the hospital or the private clinic where it takes place (institutional aspect of medicine). Yet, it remains important to keep in mind that we are dealing here with two different social systems, because this realisation reveals that the conditions of their coexistence are complicated and actual questions are problems emanating from the interaction between those two systems. For example, the proposed understanding makes it much easier to take on board the question of how institutional constraints are both imposed and resisted by practitioners, by showing that misunderstandings between doctors and health care managers are rooted in systemic differences.

For the purposes of my thesis, this differentiation shows that the regulatory orientation of law to medicine (and ultimately the constitution of medical law) should be recast in a twofold way: when the law orients itself to medicine, two distinct orientations take place. The law interacts both with the system of the economy and with the system of science.<sup>3</sup> So, in order to see exactly how medical law is constituted as a result of the primary orientation it is important to discuss both these interactions further.

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<sup>3</sup> In effect, the situation is more complicated. If one takes into account the link between the legal and the political system that the very idea of regulation entails, then it can be argued that in the legal regulation of medicine at least

## 1) The institutional dimension of medicine: the economic system.

The argument that the institutional dimension of medicine should be understood as emanating from the economic system is based on a rather straightforward syllogism. The very notion that medical care (which is the core of the technical aspect of medicine) can only be provided on the basis of a systematic organisation of the conditions of its provision transforms it into a particular kind of service. Consequently, the precise institutionalised mode of its provision becomes a significant question that requires relevant decisions to be made. Naturally, the need to take such decisions becomes acute mainly because of the problem of scarce resources: it is the scarcity of the material resources necessary for the actual provision of medical care that renders the problem worth investigating.<sup>4</sup> In a utopian society characterised by infinite resources, the problem of deciding on the conditions of the provision of medical care would be almost totally minimised. Since this is not the case in the real world, the issue of scarce resources comes to the forefront and as soon as this happens we are plainly within the domain of economics.<sup>5</sup> To support this claim let me just say that the relevant debate is almost exclusively determined by economic reasoning. For instance, the history of the organisation of health care provision in the UK is almost completely shaped by economic arguments,<sup>6</sup> which are dominant whatever the “level” of the allocation of resources.<sup>7</sup> Even when different political agendas underlie the relevant decisions and when conflicting economic perspectives are in play, it remains the case that it is economic rationality that very much determines how the provision of medical care is actually organised.

From a systems-theoretical perspective, this directly suggests that the problem of the legal regulation of the institutional dimension of medicine must be couched in terms

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four systems are simultaneously at play (namely the political, the legal, the economic and the scientific system) and accordingly that a plurality of systemic interactions should be considered.

<sup>4</sup> Let me stress here that the problem of the scarcity of resources is indeed very much present in the actuality of medical law: recall my analysis of *R v. Cambridge District Health Authority, ex p B* in the penultimate section of chapter 2.

<sup>5</sup> For the well-established claim that the management of scarce resources is the fundamental problem of economics see the general discussion in D. Begg *et al.*, *Economics* (8<sup>th</sup> edition, London: McGraw-Hill, 2005), pp. 6ff.

<sup>6</sup> See the analysis in R. Baggott, *Health and Health Care in Britain* (3<sup>rd</sup> edition, New York: Palgrave, MacMillan, 2004), chapters 4, 5 and 6.

<sup>7</sup> I use, here, the term “level” to indicate that that the problem of scarcity of resources appears in different contexts, which have to be taken into account by the relevant economic decision-making. For instance, different decisions have to be taken if the question of allocation appears at the national or the regional level, as a problem of choosing between particular services, or even as “choosing” between different patients. This differentiation indicates further that a strong ethical dimension is present here. For the relevant debate, see J. Harris, “Unprincipled QALYs” (1991) 17 *J Med Ethics* 185 and A. Williams, “Cost-effectiveness Analysis: Is It Ethical?” (1992) 18 *J Med Ethics* 7.

of the interaction between the legal and the economic system. Accordingly, the autopoietic, self-referential character of the economic system must be taken into account whenever the legal regulation of the economy is attempted. Just to provide the shortest of introductions,<sup>8</sup> the identity of the economy as an autonomous system is determined by using "payments" as its distinct elements, by using "prices" as its particular structures and by elaborating on concepts like "profit" and "efficiency". Additionally, it integrates its own mechanisms of self-description that take the form of economic theory and economic policy. It is exactly the significance of the latter that allows a range of different options to be employed by the economic system that may vary considerably.

It is precisely the conclusion that the regulation of the institutional dimension of medicine ultimately refers to the relationship between the law and the economy that justifies why from now on I will discuss exclusively the technical dimension of medicine. The reason for this choice is that the interaction between the legal and the economic system is in itself a distinct subject that necessitates a very systematic and complicated analysis that has already been thoroughly explored.<sup>9</sup> On the contrary, the interaction of law with the technical dimension of medicine is so far significantly under-theorised. In addition, I have earlier depicted the technical aspect of medicine as the *core* of medicine as jurisdiction, while the institutional aspect is only as a complementary facet of the problem. As far as the constitution of medical law is concerned this means that it is primarily the interaction of law with the technical aspect of medicine that mainly determines the constitution of the discipline. The simultaneous orientation to the economic system remains, of course, significant but –to provide a metaphor– it exercises a more "shadowy" influence for the constitution of the discipline. This influence becomes more obvious when explicit decisions that have to do with the allocation of recourses are judicially challenged and when this is the case, again the economic rationality prevails.

Consequently, in the following sections I will focus my attention only on the technical dimension of medicine: I will identify it as a social system, I will explore the relevant structural coupling, and I will discuss the constitution of medical law only in terms of the interaction of the law with this system.

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<sup>8</sup> For further analysis of the economic system, see G. Teubner, *Law as an Autopoietic System* (Oxford: Blackwell, 1993), p. 75 and his case study on corporate governance in pp. 123ff.

<sup>9</sup> For instance, see amongst others N. Luhmann, *Die Wirtschaft der Gesellschaft* (Frankfurt, 1990a).

## 2) The technical dimension of medicine: medicine as a subsystem of science.

Let me begin by restating what has probably been obvious in the course of the thesis. From a systems-theoretical perspective, medicine should be perceived as a subsystem within the social system of science. This should not come as a surprise. The general sociological theorising about medicine has been consistently arguing that its most important transformation in the course of modernity is its gradual integration into the realm of science.<sup>10</sup> This being the case, any attempt to make sense of medicine in terms of systems theory must be based on an initial exploration of the system of science.

This is not necessarily an easy task. Indeed, it has plausibly been argued that there exists an extreme plurality of accounts of what science is about, namely as many as there are philosophers of science.<sup>11</sup> However, and especially from the point of view of systems theory, two features of the system of science can be identified quite safely. The first is that science acquires its identity as an autonomous social system through its particular binary code: this takes the form of the guiding distinction between true and false. Communications emanating from the scientific system make sense of the world on the basis of this distinction: speaking scientifically, something can only be true or false. This basic distinction is also responsible for the second particular characteristic of the system of science, namely that it operates in terms of *cognitive expectations*. As I have already argued previously, these are expectations that learn from disappointment: whenever a scientific thesis about what is true is proven mistaken, the content of the expectations that have been shaped in accordance with the original thesis changes.

Medicine, being a subsystem within the system of science,<sup>12</sup> shares these basic features. Therefore it fundamentally employs the same basic distinction (code) and is characterised by cognitive expectations. However, this does not mean that this is all that can be said about medicine as a social system. The argument that I want to pursue here is that although it is a subsystem of science, it still retains some particular characteristics that render it quite an exceptional case. This does not mean that medicine—at least at the current moment in time—is a totally autonomous system. On the contrary, since all its operations are ultimately determined by the binary code of the system of science, medicine remains embedded in science. However, within social systems subsystems can

<sup>10</sup> For this discussion, the reader is referred to the relevant sections of chapter 1.

<sup>11</sup> See G. Edmond, "Judicial Representation of Scientific Evidence" (2000) 63 *Modern Law Review* 216, p. 251.

<sup>12</sup> For a very detailed analysis of the system of science, see N. Luhmann, *Die Wissenschaft der Gesellschaft* (Frankfurt: 1990b). Also the short but informing discussion in J. Paterson's, "Trans-science, Trans-law and Proceduralization" (2003) 12(4) *Social & Legal Studies* 525, pp. 531-532.



be identified, which feature a variable degree of what can be called quasi-autonomy. These subsystems acquire this autonomy by their unique use of particular secondary distinctions and by their ability to construct through them internal environments within the general system to which they belong.<sup>13</sup> My claim is that medicine is exactly such a subsystem.

Drawing again on the sociological discussion in chapter 1, the particularity of medicine as a subsystem can be traced to its gradual transformation from art into science. It has been suggested there that even if this transformation is essentially complete, some elements from the pre-scientific era of medicine still linger in the background. The relevant literature insists on a number of such elements, notably on the (sometimes) intuitive character of medical diagnosis, on the possibility of trust between doctors and patients etc. For my purposes, the most significant of the elements that can be attributed to the period when medicine was indeed an art is its essentially *task-oriented* nature. It is very much embedded in the societal perception of what medicine is about, that not only is medicine a particular, specialised type of scientific knowledge, but also that the bearer of this knowledge, the doctor, is to apply this knowledge when performing particular tasks, the stereotypical one being the provision of medical care to a patient. This is not to say that the distinction between “knowledge” and its “application” is a clear one, not even that this distinction necessarily holds.<sup>14</sup> My point is only that medicine belongs to the realm of “applied science” and that this perception is justified to a significant degree on the basis of a pre-scientific understanding of what medicine is about.

From the point of view of systems theory, what I have just said ostensibly appears to generate a problem. If medicine is itself a social system, namely a system that consists of communications, the idea of task-orientation that implies an orientation to *action* must somehow be accommodated. Yet this is not a problematic situation. This lingering task-orientation constitutes simply the “subject” of the system of medicine, in other terms the field in reference to which the system of medicine generates communications through its particular mode of observation. Of course, how exactly this field is constituted is itself defined by the communications of the system, which in this sense (like any other system) creates its own field internally. Along these lines, it is unproblematic to assert that the system of medicine defines its field in terms of tasks *as* an action system.

<sup>13</sup> This possibility can be described as second-order autopoiesis. For an introductory analysis, see E. Christodoulidis, 1998, pp. 86-87 with many further references.

<sup>14</sup> For further discussion of this complicated issue, see M. David, *Science in Society* (New York: Palgrave, MacMillan, 2005), pp. 35-38.



Another way of understanding how medicine integrates this task-orientation is through the concept of self-description. I have already discussed how mechanisms of self-description guarantee the continuation of the identity of any system by allowing the system to make sense of itself in particular ways. Through self-description, any system can define a particular domain of action as its own field of reference. In the case of the legal system this idea has already been further elaborated. Both Luhmann<sup>15</sup> and Deggau<sup>16</sup> have argued that legal communications, especially those originating from the doctrine, often describe the law itself as an action system, usually with the aim to justify more easily the dynamic character of legal change. My argument here is that the subsystem of medicine does essentially the same thing: it allows self-descriptions, the content of which is that medicine is oriented to particular tasks (actions), so that it can easily accommodate the perception of it as a task-oriented enterprise.

In line with this task-orientation, a set of additional elements further attaches to medicine its unique character as a special subsystem within science. To begin with, its communications are essentially particularistic in nature: they are constantly oriented to what the system has identified as the task to be performed.<sup>17</sup> To go a step further, this intense *particularism* has a very specific impact on the way that the subsystem of medicine perceives the dimension of time. In effect, it is not time in general that matters, but only the time dimension that is significant for the task at hand. It is easier to understand this proposition by substituting the term "task" with the term "medical case".<sup>18</sup> The way that medicine perceives time is constantly mediated by the particular time frame that is significant from the point of view of the medical case that constitutes the subject matter of the relevant communication.<sup>19</sup> In the time frame defined by the relevant medical case, it is the end point that is of primary significance, because it is the desired end result (defined as desired according to the conceptual apparatus of the medical system of course), which determines everything that happens within its range. This particular perception of time is further embedded in the way that the subsystem of medicine utilises

<sup>15</sup> See N. Luhmann, "The Unity of the Legal System" in G. Teubner (ed.), *Autopoietic Law: A New Approach to Law and Society* (Berlin: de Gruyter, 1988), p. 17.

<sup>16</sup> See H.G. Deggau, "The Communicative Autonomy of the Legal System" in G. Teubner (ed.), *Autopoietic Law: A New Approach to Law and Society* (Berlin: de Gruyter, 1988), pp. 128-151, at p. 141.

<sup>17</sup> Another way to express the same idea is to say that the medical system is characterised by the use of short-term *purposive* programs.

<sup>18</sup> Let me remind the reader that in my discussion regarding medicine as jurisdiction I argued that the management of medical cases (identified under the shorthand "medical care") represents the core of medicine.

<sup>19</sup> A very useful distinction in further elaborating the idea presented in the text is that between "perspectival" and "analytical time". The latter concept simply indicates the difference between past, present and future; the former insists that this difference must be integrated on the perception of what counts as time frame for a particular situation, event, individual etc. For further discussion of this idea, see N. McCormick, *Rhetoric and the Rule of Law: A Theory of Legal Reasoning* (Oxford: Oxford University Press, 2005), pp. 214-216.

a significant number of the secondary distinctions that it uses in its communications. These distinctions are crucial for the identification of medicine as a subsystem, since they constitute the basis on which medicine observes reality and therefore are part of any of the system's operations. Additionally, it is on the basis of these distinctions that medicine elaborates its internal structures and acquires the ability to generate and integrate its own thematisations and ultimately to refine its own, particular mode of programming.

It goes without saying that medicine, as any system, utilises a wide range of distinctions in terms of which it observes the world. However, a number of them are especially significant, in the sense that it is they that primarily establish the autonomy of medicine as a sub-system within science. My claim is that three sets of distinctions play this role, namely health v. illness, doctor v. patient and success v. failure.

On the basis of the distinction between health and illness the system of medicine acquires its particular way of observation and through that, it stabilises a set of particular themes and concepts in terms of which reality becomes meaningful. By identifying health and illness as two distinct states, medicine becomes able to generate the concept of *diagnosis*, in terms of which the two values of the distinction are allocated in particular instances and the concept of *therapy*, according to which the conditions for the transition from the negative to the positive state are defined.

Through the distinction between doctor and patient, the system of medicine observes the actors that it defines as relevant for its internally delineated field. It is only in terms of the system of medicine that an individual becomes a patient, namely a carrier of a condition that is meaningful as an instance of the negative value of the previous distinction. Similarly, only through medicine does it make sense to identify someone as a doctor, namely as the person responsible for ensuring the transition of the patient from a state of illness to a state of health, on the basis of applying scientific knowledge.

Intrinsically linked with this transition is the distinction between success and failure. According to this distinction, the system of medicine allows for a meaningful processing of the possibility that the desired transition from illness to health is not achieved. Using the distinction between success and failure it becomes possible for the system to register an evaluation of the outcome of actions that aim at achieving a state of health, as this is defined in terms of the original distinction between health and illness. The possibility of failure is further captured by the particular thematisation of the notion of *medical risk*: through this concept the system of medicine acquires the ability to communicate about illness not as a state that will ultimately be transformed into a state

of health, but as a state that will *possibly* be so. This is crucial because through the concept of risk the system highlights an intense degree of fluctuation between the positive and the negative value of the initial distinction and ensures the registering of the awareness that things may go wrong.

With these remarks regarding the distinctions and the concepts in terms of which the system of medicine observes reality, I have concluded my proposition on how medicine can be perceived as a social system. However, this is just the first step in exploring its relationship with the legal system. The next problem that has to be addressed is the question of structural coupling between the two, since only if this is achieved as a structural possibility can the regulatory orientation of law towards medicine have any impact at all. As Teubner has shown in his “regulatory trilemma”, the lack of structural coupling implies systemic indifference and when this happens regulation collapses. Within these lines, the subject matter of the subsequent section of this chapter is exactly the structural coupling between law and medicine. Although this is a distinct question, let me just say (in anticipating and introducing what will be said there) that the concept of *risk* that I just advanced is the key to understand how this structural coupling is achieved. Let us see how.

### C. Structural coupling through medical risk.

Risk has become such a popular notion in modern sociology<sup>20</sup> that it should come as no surprise that in a sociological thesis such as this, it finds a place.<sup>21</sup> Yet, in what follows I will use the concept only as a working device to argue a particular point regarding the structural coupling between law and medicine. In doing this, I will use some insights provided by those theories that identify societies of the era of late capitalism as *risk societies*,<sup>22</sup> and I will insist on the link between risk and uncertainty.

For theorists like Ulrich Beck and Anthony Giddens, risk society is characterised by the constant increase of human intervention towards nature and by the intensification of human *control* over natural eventualities. Societies of late modernity are no longer determined by the impact that nature may have upon them, but by the impact that their

<sup>20</sup> For a very good overview, see D. Lupton (ed.), *Risk and Socio-Cultural Theory: New Directions and Perspectives* (Cambridge: Cambridge University Press, 1999).

<sup>21</sup> The notion of risk has already been utilised in interesting contributions both to medical law and to medical ethics. For the former see D. Morgan, *Issues in Medical Law and Medical Ethics* (London: Cavendish, 2001) and for the latter D. Dickenson, *Risk and Luck in Medical Ethics* (Cambridge: Polity Press, 2003).

<sup>22</sup> See the seminal work by U. Beck, *Risk Society: Towards a New Modernity* (London: Sage, 1992) and A. Giddens, *The Consequences of Modernity* (Cambridge: Polity Press, 1990).

control has upon nature.<sup>23</sup> As this control increases it reaches a point of reflexivity,<sup>24</sup> in the sense that instead of solving problems and managing natural and social eventualities it gradually starts itself to produce new problems, namely new risks.<sup>25</sup> This reflexive production of risk can be attributed to the advances in science and technology, which simultaneously respond to a range of human problems *and* are responsible for the creation of new ones.<sup>26</sup> As a result of this reflexivity, a set of new political, economic, ethical and institutional structures have been developed that are meant to consider and counter risk. This transformation is supposed to be of such a degree that the "risk society" is identified as a new form of society.

According to this theorising, the situations that exhibit risk are exactly those that are characterised by a certain lack of control over their content. To paraphrase, a situation is risky exactly when its outcome is *uncertain* because of lack of control. Naturally, uncertainty does not entail that the participants in a situation cannot develop expectations regarding the possible or even the desired outcome; in fact without contingency "expectations" would not make sense. So, the participants will indeed behave in accordance with their expectations even in risky situations.

By analysing risk in such a way, it becomes obvious that it is very much a time-related concept. It makes sense to speak about risk, uncertainty and expectations only in terms of two different moments in time: a present moment in which an assessment about the possible outcome of a situation is made and a future moment when this assessment proves to be correct or not. In this respect, the concept of risk strongly "crystallises" the sociological importance of transitions between different moments in time. It is on the basis of this remark that the concept of risk can be used to clarify the possibility of structural coupling between law and medicine.

Let me revisit the social system of medicine, in relation to this conceptualisation of risk. In discussing medicine, I argued that because of its task-oriented nature and of the significance of the particular time frames that medical cases designate, the crucial distinction between success and failure comes to the surface. In terms of this distinction a concept of medical risk emerges. In effect, this concept exhibits all the characteristics that the generalised concept of risk just presented reveals: medical risk is related to uncertainty and expectations (for instance it is uncertain whether a patient will be healed,

<sup>23</sup> This transformation is usually depicted as the "end of nature" and is connected with the development of science and technology. See, in details, A. Giddens, "Risk and Responsibility" (1999) 62 *Modern Law Review* 1, p. 3.

<sup>24</sup> For a detailed account of this particular use of the concept of reflexivity, see A. Giddens, 1990, pp. 36ff.

<sup>25</sup> For further analysis of how this has happened see U. Beck, 1992, chapter 1.

<sup>26</sup> Mainly because the application of modern science is based on short-term knowledge, whereas the potential for future prediction is still very limited.



although it can be expected that this will happen) and is also ultimately linked with the actual or projected transition between two different points in time. Accordingly, the difference between separate points in time and the need to manage this difference is structurally embedded in the medical system through the notion of medical risk.

If we now turn to the legal system, we can see that the law is also aware of the difference between moments in time and is actually using it in a particular and also structurally embedded way. As the analysis of the function of the law made plain, the law stabilises normative expectations and this necessarily presupposes its ability to use its *present* decisions and norms in order to bind *future* behaviour. In doing this, the law also manages the difference between two separate points in time. Accordingly, both the legal and the medical system communicatively deal with transitions in time and –to put it in more general terms- they both deal with the handling of *risk*. It is exactly this “commonality” that ensures that the structural coupling between law and medicine is possible at the outset. I insist that this is only a *minimal structural similarity*, because nothing in my discussion should be taken as implying that the two systems handle risk in a similar way. My moderate suggestion is just that structural coupling is possible because of this commonality: medical risk can be seen as an opportunity structure towards which the law can be oriented or on the basis of which communications that emanate from one of the systems can simultaneously be processed by the other. This argument regarding the possibility of structural coupling implies merely that the regulatory orientation of law towards medicine can have *some* impact, in the sense that the possibility of systemic indifference can be avoided through this structural coupling. Nothing more than this moderate conclusion should be assumed here.

## **D. The internal constitution of medical law.**

### **1) Preliminary remarks.**

Having concluded the identification of medicine as a social system and the delineation of a minimal structural affinity that establishes the structural coupling between law and medicine, it is now time to proceed to the core of my reassessment of the constitution of medical law. I will do so based on the concepts that I have developed in the previous chapter and on the fundamental premise that medical law is constituted as a discipline as a result of the regulatory orientation of law to medicine. In the process, I will also re-



assess the conclusions reached in the first two chapters of the thesis, since both what the doctrine proposes and what the empirical material reveal are already tangible results of the link between law and medicine. Therefore they have to be recast in accordance with the general theoretical re-assessment that I am proposing and indeed must be considered seriously as an existing indication of how law and medicine interrelate. In this light, what follows is not simply a “translation” of what has already been said in systems-theoretical terms, but a substantial reworking of arguments that are already present within the discipline.

In the next section of this part I will focus my attention on the doctrinal propositions regarding the subject matter of medical law. From then on, all the subsequent discussion will be related to the empirical material that I presented in detail in chapter 2. This should not be seen as an arbitrary and uneven distribution of the structure of this part. This over-insistence on the empirical material is justified on the basis of my main thesis that the constitution of medical law is primarily controlled according to the interplay between redundancy and variation. This interplay is expressed in the exact articulation of the norms that constitute the discipline and thus it is at this level that the substance of my proposals must be pursued.

## **2) The doctrine revisited.**

So, let us return to the doctrine and to its “implausible” propositions on the basis of which medical law has been constituted as a discipline. The thrust of my critique against these propositions is twofold: first, that even on their own terms they fail to provide an adequate conceptualisation of the discipline, and secondly, that they are based implicitly on the input-output model of the open systems approach and that they ultimately attempt to organise medical law through external references. Both the idea that medical law is about medical ethics and the view that medical law is a vehicle for the protection of the patient in accordance with the discourse of human rights, utilise external themes as the main organising principles of the discipline. This assertion is problematic because of the self-referential character of the law and by necessity of all its branches. The law operates exclusively in an internal way and thus everything that happens within the law – including the constitution of new disciplines- is determined only in accordance with internal references.

Still, there are three valuable insights that these doctrinal propositions offer, which are necessary for any attempt to make sense of the constitution of medical law as an internal process. The first refers again to the doctrinal reliance on externalities. Although external references cannot provide organising principles as such, they still provide the trigger that irritates the legal system. It is only because of the interaction of the legal system with its environment, which takes place whenever the law responds to the external “noise”, that an internal restructuring of the legal system occurs and that medical law ultimately emerges as a distinct subject. In this respect, the doctrine correctly highlights the importance of the *link* between law and medicine for medical law, although both approaches’ over-reliance on the externalities of medicine renders their understanding of the field problematic.

The second significant insight refers to the particular task that the doctrine performs within the legal system. Whatever the plausibility of its content, doctrinal analysis is an internal mechanism according to which the law makes sense of itself, in other words it is a mechanism that contributes to the self-description of the legal system.<sup>27</sup> This means that both the particular doctrinal identification of the discipline of medical law and the principles on which this is based become part of the internal memory of the legal system. This is not to say that the legal system does not control how its memory is constructed, nor that the external references of the doctrine do not become internalised: the opposite is the case. For instance, ethical principles like autonomy or beneficence are transformed into the legal norms of consent to treatment and of the “best interests” test.<sup>28</sup> However, even under the guard of this internalisation the doctrine shares in the conceptual matrix of the law. In this respect, the doctrine is linked with the redundancy of the legal system since the self-descriptions to which it contributes are used in a recurrent manner by the system: in accordance with premises provided by the doctrine, legal norms are interpreted, relevant conclusions are reached and the link of current legal communications with future ones is further expanded.

The third insight is very much linked with the previous one. True, the externalities of the doctrine become internalised and the memory of the legal system is determined in accordance with their internal transformation. Yet, the initial direct orientation of the doctrine to externalities remains present as a kind of “echo” within the horizon of medical law. Because of its doctrinal aspect, medical law carries with it an

<sup>27</sup> Recall, here, the analysis of this notion in chapter 3.

<sup>28</sup> This point is linked with the more general process, in terms of which the law uses the distinction between external and internal reference. For a much more elaborate analysis of this issue, see N. Luhmann, 2004, pp. 346ff.

implicit “burden”: the doctrinal insistence on medical ethics and on professional power attaches to medical law an under-defined dimension of “moralisation” and “politicisation”<sup>29</sup> that also shapes to some extent the discipline. In order to see how exactly this is happening and what its repercussions are for medical law, we need to investigate in more detail what is going on in the empirical reality of medical law through the lenses of redundancy and variation. It is to this issue that we will now turn our attention.

### 3) Redundancy and variation in action.

In my discussion in chapter 3, I insisted that the main mechanism that determines the internal constitution of new disciplines within the law is the interplay between redundancy and variation. Through this interplay the law determines exactly how it copes with environmental complexity and how it organises its internal complexity in responding to environmental noise. Redundancy guarantees the strength of the existing memory of the legal system, while variation pushes towards novelty by allowing exceptions to redundancy: it tests new thematisations, it links existing norms in new ways and it also controls the generation of new norms. In terms of medical law, this means that variation controls the themes that medical law will deal with and the particular norms that will become operational towards them. Simultaneously, redundancy links these novel developments with the already existing matrix of the law, establishes how new norms replicate older ones and ultimately what new themes are treated *as* new by the legal system. During this process some medical issues are internalised; some others are filtered out.

Through the notion of the regulatory trilemma an additional concept was added to this scheme, namely “disintegration”: the implication here is that when the law regulates other social fields the interplay between redundancy and variation may produce pathological effects, in the sense that the autonomous character of the law becomes endangered. This implies that it is possible for the balance between redundancy and variation to be *overstrained* and in turn, this can only be conceptualised in terms of the unique function of the law. When variation intensifies to such a degree that the law cannot generalise normative expectations in a stable manner, for instance because of the constant generation of new norms and the constant integration of new themes that

<sup>29</sup> I borrow these concepts by G. Teubner, “*Altera Pars Audiatur: Law in the Collision of Discourse*” in R. Rawlings (ed.), *Law and Economy* (Oxford: Oxford University Press, 1997), pp. 149-176, at p. 152.

cannot be accommodated by redundancy, the normativity of law is undone: whenever the law provides norms in a very particularised manner, its unique reduction achievement of the law is lost. In this sense, an intense increase in variation can be seen as systemic entropy that intensifies the possibility of disintegration.

In applying this theoretical apparatus to the empirical reality of medical law, we can acquire some very illuminating insights as to how the interplay between redundancy and variation has so far shaped the constitution of medical law as a discipline. In order to do so, it is necessary to refer back to the initial conclusions reached at the end of chapter 2. There, in elaborating on what I have identified as the “complexity” of medical law, I argued that medical law is characterised by a random division between legislative interventions and adjudicative solutions to medical problems; that from the two it is adjudication that primarily carries the discipline forward by ensuring the involvement of the law with novel situations, especially since judicial decisions are very much aware of the particularities of concrete scenarios and provide solutions on a case-by-case basis; finally, that as a result the whole edifice of medical law is characterised by a high degree of substantive rationality, which is very much linked with the “moralisation” and “politicisation” of the discipline rooted at the doctrinal level.

My claim here is that three “theses” represent the tangible result of how redundancy and variation have determined the constitution of medical law and indicate what have been the repercussions of law’s exposure to the system of medicine. Especially the very strong judicial tendency within medical law for deciding on a case-by-case basis and for being particularly aware of the specific character of the case at hand, with the resulting intensification of substantive rationality is not only an indication of variation at play, but also -and more crucially- a reminder that *in medical law the normativity of law is under strain*. An increase in variation can indeed ensure that case-by-case reasoning and substantive rationality become the main “trend” within medical law; however – and especially if we see this from the point of view or programming- both these features abandon conditional programmes (which are essentially compatible with legal normativity) in favour of purposive programs that orient the legal system towards achieving concrete results in concrete scenarios. Given that the legal system exists in time, a constant shift towards this type of legal pronouncements could indeed generate “dangerous” disintegrative effects for the law. It goes without saying that the term “dangerous” is used here in a strictly technical sense: I do not mean that medico-legal adjudication will cease to exist, but that a shift in the nature of the process of decision-

making will undermine the particular reduction achievement of the law. Courts will still adjudicate in medical law: their solutions, though, will not exhibit these characteristics in terms of which law is autonomous *as* law through the uniqueness of its function.

Here then is an interim conclusion regarding the constitution of medical law. This is controlled by redundancy/variation as the law is irritated by medicine in the process of regulation. To begin with, their interplay ensures the particular way that medical law internalises medical themes: in this process, it is not necessary that all the signals that medicine emits will be internalised by medical law, nor that the internal complexity of the law will totally mirror the complexity of medicine. Especially redundancy guarantees that some signals will remain unnoticed. Simultaneously, variation pushes medical law towards the opposite direction, namely towards the *intensification* of its internal complexity; this can already be noticed in the case-by-case adjudication within the discipline and in the density of its substantive rationality, on the basis of which novel situations from medicine are legally countered. This increase in variation generates disintegrative effects within medical law, in the sense that legal normativity is threatened. In medical law, the generalisation of stable normative expectations is not necessarily an uncontested feature of the discipline.

At this stage this is a general conclusion, still framed in abstract terms. Thus, and in order to further clarify the argument, in the next three subsections I will pick up again three particular “themes” of medical law (identified as themes necessarily internally) that I presented in depth during the analysis in chapter 2 and I will investigate how my conclusions can further be tested.

#### **a) Medical negligence.**

In discussing the social system of medicine, I argued that one of its major distinctions is the one between success and failure. According to this distinction the medical system communicates about the final “result” of a medical case; essentially it assesses this result in a way that a) defines whether more has to be done about this case and b) explains the occurrence of this particular outcome. Especially in the case of failure, the medical system can generate further communications on the basis of which it interprets this failure as resulting from a tripartite cluster of possibilities, namely as an unavoidable eventually, as an accidental occurrence or as attributable to a scientific mistake on the part of the doctor.



In the process of the legal regulation of medicine, the law becomes irritated by this communicative network of the medical system and responds by thematising the concept of medical negligence. In doing so, it attaches legal significance only to the last of the possibilities just mentioned. Already we can identify a process of legal selectivity here: from all the possibilities that medicine attaches to the initial distinction between success and failure, the legal system selects only one that will be dealt with as legally significant. The exact internalisation of the initial trigger is controlled by redundancy: in the matrix of the law, the concepts that are relevant to faulty performances revolve around the core notion of responsibility and the relevant concept of negligence. Through redundancy legal responsibility and negligence are replicated in response to this external noise and medical negligence as a new – but simultaneously old- theme emerges.

If we look more closely at how exactly the law deals with medical negligence we have to consider, further, the substantiation of the standard of care. The problem here is that the law has to develop a criterion in terms of which what a health practitioner did can be considered as negligent or not. This is not of course a new problem for the law, since it is present whenever the question of negligence comes to the surface. Yet, the assessment of the responsibility of a medical practitioner is particularly problematic because whatever a doctor does is meaningful only in terms of the scientific system on the basis of which she, herself, conceptualises her actions. Accordingly, the legal assessment of this responsibility (and ultimately the legal norm that would substantiate the relevant standard of care) has somehow to open up to the internal horizon of meaning of the scientific system.

The problem here is that the law does not have concepts that are adequate in themselves to “incorporate” the internal criteria of the scientific system that the assessment of medical negligence necessitates. Accordingly, variation comes into the picture and creates an exception to the general rules of standard of care:<sup>30</sup> for medical negligence the test as defined in *Bolam* is that “...of the ordinary skilled man exercising and professing to have that special skill”.<sup>31</sup> The exception is that through the *Bolam* test the substantiation of the standard of care is thrown back to the medical system: the law, through this formal formulation of the relevant rule invites the medical system to activate its criteria and in doing so, it incorporates criteria it has no “control” over into the legal

<sup>30</sup> For an analysis of the reasons that sustain the claim that professional negligence is an exceptional category within the general law of negligence, see J. Healy, *Medical Negligence: Common Law Perspectives* (London: Sweet & Maxwell, 1999), pp. 63-64.

<sup>31</sup> Per McNair J in *Bolam v. Friern Hospital Management Committee* [1957] 2 All ER 118 at p. 121. Let me remind the reader, here, that in chapter 2, I also analysed a series of cases that further sophisticated the test.

internal horizon. If we go back to the notion of the regulatory trilemma this is an obvious example of disintegration, since a legal structure (the standard of care) is colonised by the system under regulation. Furthermore, from the point of view of the function of law, this amounts to a loss of function: the law here stabilises expectations only in a very formal and very limited way, namely only by guaranteeing that doctors will be held responsible for negligent actions *in accordance with their own assessment of what constitutes negligence alone*. This expectation is based on a circular paradox (a doctor is negligent when doctors think he is negligent) that does not allow for a legal criterion on the basis of which this circularity can be solved.

More recent judicial decisions (in other words more recent legal communications) have attempted to compensate this “loss of function” by bringing the criterion of the standard of care, at least partially, back to law. For instance, in *Bolitho*,<sup>32</sup> the *Bolam* test was recast in such a way as to allow for some legal assessment of the professional determination of the standard, when this is essentially unreasonable. However, as the exact impact of this decision is still unclear, it is not yet the case that the colonisation of law by the medical system in terms of the *Bolam* test has been countered.

#### **b) Consent to treatment.**

In the course of this thesis, I have repeatedly referred to the importance of autonomy for the discipline of medical law. Its importance surfaces both within the domain of medical ethics and within arguments from the tradition of human rights and is primarily expressed on the claim that the patient is an autonomous agent and as such she has to be respected. This claim is ever present within the domain of medicine and co-determines the interaction between health care professionals and patients.

From the point of view of medical law, autonomy is *internalised* into a legal norm according to which the legality of medical operations depends on the consent of the patient involved. Legal consent is the concept through which the law embraces the notion of autonomy and is very much relevant to a wide range of scenarios that entail the involvement of the law. This internalisation of autonomy as consent to treatment is again determined by redundancy. The idea that the individual is worthy of respect and of legal protection as an individual is also a fundamental conceptual achievement of western legal systems. Western law is very much oriented to the value of the individual and

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<sup>32</sup> See the reasoning in *Bolitho v. City & Hackney HA* [1997] 4 All ER 771.

accordingly, the category of the *legal person* is already integrated into the basic structures of the law.<sup>33</sup> Therefore, the legal system has only to refer to its internal memory in order to replicate an external theme that is already crucially compatible with its own concepts. It is here that redundancy appears: the law revisits its pre-existing matrix of memory and it easily integrates what is initially an externality by linking it with internal concepts and structures towards which the external theme exhibits a high degree of affinity. From the point of view of the legal system, patient's autonomy is nothing new; rather, it is simply a restatement of the pre-existing legal idea of the legal person.

Although this seems like an easy process of "internalisation", difficulties instantly appear. The main one is that it becomes necessary to develop auxiliary legal concepts in terms of which a patient can be defined as an autonomous agent and enjoy the protection that the concept of consent entails. As I have discussed in detail in chapter 2, the relevant case law stresses very much the notion of *competence* as the main auxiliary concept: it is only the consent of competent individuals that matters.

It is exactly here that the difficulty with internalising the theme of autonomy lies. At this level, the law does not have adequate concepts to *problematise* autonomy, namely to investigate exactly the status of a patient. This is a significant issue, especially if one considers that the patient, exactly because of her status as a patient, is often in a state of reduced autonomy. This being the case, the law needs a sophisticated cluster of criteria to build into and "re-contextualise", as it were its reductions. However, the only one available is the rigid distinction between competence and incompetence. Even though it is accepted that competence is relative to the particularities of the case at hand,<sup>34</sup> the relevant provisions are underdetermined and they rely very much on the assessment of the health care professional in charge of the patient regarding her competence. Again then, the medical system (through this professional assessment) penetrates the legal system and again a "loss" of function is the price that medical law pays: as the legal system cannot accommodate a substantial test for competence, case-by-case decisions become the norm and contingent outcomes are frequent. As a result, normative expectations regarding whether the autonomy of a patient is going to be protected cannot be generalised.

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<sup>33</sup> Quite naturally, the relevant literature is indeed immense. Among many others, see F. Tonnies, *Community and Society* (East Lansing, Michigan: Michigan State University Press, 1957) and the discussion in R. Cotterrell, *The Sociology of Law: an Introduction* (2<sup>nd</sup> edition, London: Butterworths, 1992), pp. 118ff.

<sup>34</sup> The reader is referred to the relevant cases in chapter 2.

### c) The best interests principle.

The last testing ground for the constitution of medical law is the “best interests” principle. As I explored at length in the second chapter, this principle is the second major “vehicle” (apart from consent to treatment) in terms of which the legality of a medical operation is established. It is used when the patient involved is incompetent and it becomes operational in the following form: a medical intervention to an incompetent patient is legal when it is being performed in the best interests of the patient.

It should not be a surprise that this principle is present in the medical system and that it significantly co-determines the doctor-patient relationship. There it exemplifies the professional ethos in favour of beneficence in accordance to which the doctor must have the interests of her patient always in mind. Once again, then, what we are dealing with here is a process of internalisation since the law develops an internal norm by becoming oriented to a signal belonging to the sphere of medicine. Once again, through redundancy this signal is being processed against the pre-existing matrix of legal memory and the legal system responds by activating a particular normative structure that is linked with the tort of battery, namely the defence of *necessity*. The best interests principle appears as a particular expression of necessity (and this is controlled in terms of variation): a doctor that treats a patient in her best interests has a legal defence against the tort of battery that otherwise would have been committed.

This is how the best interests principle becomes “actualised” within the horizon of the legal system. Once again, though, this is not the end of the story for the obvious reasons that the formulation of the legal norm is open-ended: the rule does not provide any criteria for the substantiation of the principle. In other words, it is not registered within the norm when the best interests principle is satisfied and when it is not. Indeed, my presentation of the relevant case law in chapter 2 has shown that there is a wide discrepancy in the way that courts substantiate the principle and that a number of ways are invoked in the judicial usage of the principle. In an essential way, its exact substantiation is determined by the particularities of the case at hand.

If we consider these findings of the second chapter from the point of view of the argument that I am developing here, it becomes obvious that this formulation of the principle and its judicial usage has disastrous effects for the normativity of law. Since the principle is substantiated on a case-by-case basis, we are dealing with a framework of extreme variation that cannot be countered by any invocation of redundancy. In effect,

the law totally opens up and totally resigns from the invocation of any legal criteria in designating what exactly the normative content of the principle is. In a sense this increases the flexibility and the substantive orientation of the use of the principle, since what is actually happening here is the substitution of conditional by purposive programs:<sup>35</sup> it is the particularity of the situation that defines its purpose and according to which the best interests of the patients are defined. Again the price is too high: again the normativity of law is lost and once again the distinct character of law is endangered. If one considers the very wide invocation of the best interests principle, this is a very serious situation indeed. In effect, it is exactly here that medical law as a legal discipline is strained the most.

#### 4) On the stabilisation of expectations (again).

One needs to return to the function of law, in order to show how this also has a direct impact on the constitution of medical law. In a sense this is just a complementary argument to what I have already said about redundancy/variation and their relation with the function of law, hence the term “direct” impact that I employ here.

Given that law’s function is to stabilise normative expectations, its regulatory impact is essentially determined by the actual observance of the expectations that it generates. If one takes a step back, what is important here is that the production of legal norms in terms of which normative expectations are formulated is always conditioned upon the relative complexity of law’s environment at the moment of their production. The interesting question is what happens when this state changes. The usual answer is that the law adapts to this change by producing new norms that are again compatible with the state of the legal environment. However, this answer cannot accommodate the possibility of changes in the environment that happen at a faster pace than that according to which the legal system can adapt to change. This is stereotypically the problem with the rapid development of scientific knowledge. In this situation, legal adaptation is not enough and what comes to the forefront is the fate of normative expectations that do not correspond with the environmental conditions on the basis of which they came into existence.

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<sup>35</sup> It can be argued that what we are having here are purposive programs “nested” into conditional programs. For further analysis, see J. Paterson, “Reflecting on Reflexive Law” in M. King and C. Thornhill (eds.), *Luhmann on Law and Politics: Critical Appraisals and Applications* (Oxford: Hart Publishing, 2006), pp. 13-35, at p. 19, with further references.



A crucial concept in order to understand this situation is that of second-order normativity. As I discussed in chapter 3, for the law to achieve its function it is not enough only to generate normative expectations; it is also necessary to guarantee that the fulfilment of these normative expectations is itself normatively expected.<sup>36</sup> It is exactly this second-order normativity that becomes problematic when the law cannot follow the pace of scientific developments. As this inability is socially registered, it becomes apparent that the normative expectations that are still in place are not compatible with the current state of scientific knowledge. Still, these expectations are part of valid law and since they are normative in nature they will not learn by the possibility of being disappointed. Even if they are not fulfilled they will remain valid. However, their incompatibility with the environmental conditions is significant at the level of second-order normativity: this will gradually be eroded, since it will cease to be the case that it will be normatively expected that normative expectations of the first order will be fulfilled. In turn, this erosion of second-order normativity will have an impact on the normativity of the first-order: it is quite probable that first-order normative expectations will be less and less fulfilled in real terms. If this becomes a generalised stance, then the regulatory impact of the legal system is minimised, since this requires at least some level of observance of the currently valid normative expectations. Since the pace of scientific development is indeed very rapid, this is a constant problem for the regulatory potential of the legal system. Even when legal change is effected, it very soon ceases to be compatible with some new developments and so on. The legal system permanently lags behind. My argument here is that this "lagging behind" is very much embedded into the constitution of medical law.

As an obvious example of this situation, one can use the legal regulation of the scientific techniques of assisted reproduction. These techniques significantly challenged traditional notions regarding family relationships and consequently some of the main norms of family law. With the passing of the Human Fertilisation and Embryology Act 1990 the incompatibility between the previous and sparse regulatory edifice and the then state of scientific knowledge was eliminated. Yet, time passes and although science progresses, the normative edifice remains the same: the 1990 Act is still valid even after 15 years of its passing and with it the normative expectations that are based on it are still operational. Obviously, eventually the legal system will adapt to the new state of the relevant scientific knowledge. It is no surprise that already a process of amending the

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<sup>36</sup> For further analysis, see E. Christodoulidis, 1998, p. 118.

1990 Act has commenced.<sup>37</sup> Still, the problem remains: in the meantime the legal regulation is behind the current state of the area that it is supposed to regulate and even if the Act will be eventually amended it will soon start to lose the battle of pace again. As far as the constitution of medical law is concerned this example shows that although the initial legal developments respond to environmental stimuli, the passing of time constantly differentiates the state of the legal system from the state of its environment. Therefore, the legal norms pertinent to assisted reproduction are gradually much less compatible with the area that they are supposed to regulate: although medicine changes fast medical law only belatedly reacts.

### 5) An endnote: reflexivity in medical law?

In this penultimate part, I want to consider briefly the tentative idea of legal reflexivity that I introduced in the previous chapter. This should be seen as a coda to my general argument, mainly because this exciting theoretical proposition is still under-developed and because its general plausibility largely still remains to be tested empirically. However, on the assumption that the idea of reflexivity holds the reassessment of the constitution of medical law must consider the possibility of reflexive elements being present in the horizon of the discipline.

Indeed, if one considers the relevant legal material it becomes apparent that a number of institutions, established by particular statutes and regulations are very close to the idea of reflexivity and especially to a special version of it, namely the idea of *communication through organisation*. Let me remind the reader that this idea implies that it would be possible to enhance the reflexive interaction between systems if at their boundaries binding institutions are formed on the basis of which stable patterns of systemic interaction emerge. This stability would be the result of the simultaneous participation of the institution in both systems in a way such that would ensure that the parallel processing of information would be achievable in a stable manner.

In the context of medical law, I have in mind two examples of institutional settings that can be conceptualised in such a way. The first is the Human Fertilisation and Embryology Authority established by the HFE Act 1990. The main regulatory remit of this Authority is to license a number of activities that are included in the Act and that refer to medical research and to techniques of assisted reproduction. In reference to

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<sup>37</sup> For these developments, see J.K. Mason and G.T. Laurie, *Mason & McCall Smith's Law and Medical Ethics* (7<sup>th</sup> edition, Oxford: Oxford University Press, 2005), pp. 72-73.

these activities, the law refuses to regulate directly: instead it sets up an intermediary institution that acquires the authority to regulate them through licensing, by simultaneously considering both the general legal environment and the medical and scientific considerations that characterise these activities. Furthermore, the Authority has the ability to consider a wide range of factors (most notably ethical factors) in its decisions and in this respect it stands at the crossroads of a number of systems.

Similarly, such a “binding” role can be read in the newly formed Council for the Regulation of Health Care Professionals, established by the Health Care Professions Act 2002. In effect, this Council is the new authority that has to monitor the performance of the particular regulatory bodies of health care professions, with the aim to protect the interests of the patients. Its role, then, is essentially protective and it can substitute the direct regulation of health care professionals by legal norms. In this respect, it may provide an alternative way for controlling the medical profession, by operating at the boundaries of the legal and the medical system.

These are simply two examples that seem to me to justify a claim that reflexive elements are present in medical law. Similarly with the general idea of legal reflexivity it is still a matter of time to see whether they will proliferate and what exactly their impact will be for the future constitution of medical law. Like reflexivity in general, their existence provides some hope that it is possible to increase the regulatory potential of medical law without overburdening the distinct character of the legal system.

## E. Conclusion.

I introduced the discussion in this chapter, by stating that my aim was to reassess the constitution of medical law from the perspective of systems theory and by taking on board conclusions developed in chapters 1 and 2. Having reached the end of this discussion let me now sum up what this reassessment has revealed, in six distinct theses.

**Thesis one:** medical law is constituted as a distinct branch of the law *internally*, during the regulatory orientation of law towards medicine. This process primarily involves the interaction between two social systems, law and medicine, the latter being a subsystem within the social system of science.

**Thesis two:** the interaction between law and medicine is established because a structural affinity between the two exists. This affinity, that guarantees the possibility of structural coupling, is related to the concept of medical risk.

**Thesis three:** as far as the constitution of medical law is concerned the mechanisms that determine exactly how the law will respond to medicine is the interplay between redundancy/variation and the function of law. As these are internal mechanisms the doctrinal propositions that medical law is constituted as a discipline directly in accordance with external themes collapse. Externalities are important only as triggers for internal processes.

**Thesis four:** the constitution of medical law proposed here is linked with the problems that the exposure of the law to the non-legal world brings to the forefront. The notion of the “regulatory trilemma” captures these problems best and brings to the fore the possibility of *disintegration*. In the case of the interaction between law and medicine this is a real possibility: indeed medical law is a branch of the law where because of disintegration, the reduction achievement of legal normativity is actually under threat.

**Thesis five:** the result of this threat is that the regulatory potential of medical law is somehow limited, since there exists a tendency to counter disintegrative effects by ignoring a number of signals that the medical system originates.

**Thesis six:** in accordance with the tentative suggestions of reflexive law, it is possible to identify reflexive elements within medical law. These elements not only co-determine the constitution of the discipline, but also indicate that it is possible to increase the regulatory potential of medical law without furthering the problem of disintegration and “loss” of function.

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